Dokumentvorlage, Version vom 16.12.2021

Dossier zur Nutzenbewertung gemäß § 35a SGB V

Avapritinib (AYVAKYT®)

Blueprint Medicines (Germany) GmbH als örtlicher Vertreter des Zulassungsinhabers Blueprint Medicines (Netherlands) B. V.

Modul 4 A – Anhang 4-G

Avapritinib (AYVAKYT®) ist zur Behandlung von erwachsenen Patienten mit indolenter systemischer Mastozytose (ISM) mit mittelschweren bis schweren Symptomen indiziert, bei denen mit einer symptomatischen Behandlung keine ausreichende Kontrolle erzielt werden kann

Medizinischer Nutzen und medizinischer Zusatznutzen, Patientengruppen mit therapeutisch bedeutsamem Zusatznutzen

Stand: 20.12.2023

Anhang 4-G: Weitere Analysen und graphische Verläufe zu den in Abschnitt 4.3.1.3.2 gezeigten Ergebnissen der Subgruppenanalysen

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Table 35.2.1.2.2.2a
Summary of Change from Baseline in TSS of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	15	35	52	88	
Mean (StdDev)	58.46 (21.326)	47.46 (16.648)	53.18 (17.912)	55.65 (17.236)	
Median	64.93	43.31	48.26	53.99	
Min, Max	31.1, 86.3	28.6, 102.7	28.9, 104.4	29.6, 98.4	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. CxD1 score is defined as the 14-day average of TSS prior to CxD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to CxD1 visit, the CxD1 score is considered as missing for the patient. Patients with high-dose steroid use within 7 days before CxD1, or greater than 14 consecutive days at any point from C1D1 to C7D1, the CxD1 score will be set to missing and will be excluded from the ANCOVA analysis.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tss-sum-g-pp-sex-a.sas Date: 14:34/07AUG2023

Table 35.2.1.2.2.2a
Summary of Change from Baseline in TSS of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	14	33	52	82	
Mean (StdDev)	50.50 (19.939)	43.06 (16.958)	47.73 (18.730)	46.06 (18.606)	
Median	44.61	40.38	43.36	42.21	
Min, Max	25.2, 79.6	21.2, 89.4	22.6, 98.9	13.8, 92.3	
C2D1 CFB					
n	14	33	52	82	
LS Mean (StdErr) [2]	-10.10 (2.081)	-5.69 (1.402)	-4.85 (1.386)	-8.94 (1.234)	
95% CI [2]	-14.30, -5.90	-8.52, -2.86	-7.60, -2.11	-11.39, -6.50	
Difference (95% CI) in CFB [2]		4.41 (-0.32, 9.13)		-4.09 (-7.12, -1.06)	
p-value [3]		0.067		0.009	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. CxD1 score is defined as the 14-day average of TSS prior to CxD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to CxD1 visit, the CxD1 score is considered as missing for the patient. Patients with high-dose steroid use within 7 days before CxD1, or greater than 14 consecutive days at any point from C1D1 to C7D1, the CxD1 score will be set to missing and will be excluded from the ANCOVA analysis.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.1.2.2.2a
Summary of Change from Baseline in TSS of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	33	52	83	
Mean (StdDev)	46.34 (21.833)	40.03 (14.924)	45.58 (18.508)	41.40 (20.230)	
Median	43.92	38.50	42.54	41.29	
Min, Max	13.2, 84.6	16.6, 86.6	14.8, 93.8	8.9, 91.9	
C3D1 CFB					
n	15	33	52	83	
LS Mean (StdErr) [2]	-12.48 (2.704)	-8.09 (1.863)	-6.54 (1.894)	-13.18 (1.651)	
95% CI [2]	-17.92, -7.03	-11.84, -4.34	-10.28, -2.79	-16.44, -9.91	
Difference (95% CI) in CFB [2]		4.39 (-1.75, 10.52)		-6.64 (-10.79, -2.49)	
p-value [3]		0.157		0.002	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. CxD1 score is defined as the 14-day average of TSS prior to CxD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to CxD1 visit, the CxD1 score is considered as missing for the patient. Patients with high-dose steroid use within 7 days before CxD1, or greater than 14 consecutive days at any point from C1D1 to C7D1, the CxD1 score will be set to missing and will be excluded from the ANCOVA analysis.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.1.2.2.2a
Summary of Change from Baseline in TSS of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	15	33	49	82	
Mean (StdDev)	45.19 (23.704)	38.03 (15.913)	45.79 (18.595)	39.63 (21.012)	
Median	37.93	35.69	40.86	40.07	
Min, Max	12.3, 83.5	11.2, 85.0	14.6, 90.0	4.1, 92.2	
C4D1 CFB					
n	15	33	49	82	
LS Mean (StdErr) [2]	-13.10 (3.323)	-9.70 (2.289)	-6.85 (2.262)	-15.34 (1.934)	
95% CI [2]	-19.80, -6.40	-14.31, -5.09	-11.33, -2.37	-19.16, -11.51	
Difference (95% CI) in CFB [2]		3.40 (-4.14, 10.94)		-8.49 (-13.36, -3.61)	
p-value [3]		0.368		<0.001	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. CxD1 score is defined as the 14-day average of TSS prior to CxD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to CxD1 visit, the CxD1 score is considered as missing for the patient. Patients with high-dose steroid use within 7 days before CxD1, or greater than 14 consecutive days at any point from C1D1 to C7D1, the CxD1 score will be set to missing and will be excluded from the ANCOVA analysis.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.1.2.2.2a
Summary of Change from Baseline in TSS of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	33	47	85	
Mean (StdDev)	45.52 (23.301)	35.87 (15.704)	45.56 (19.149)	38.07 (21.040)	
Median	42.86	32.79	41.43	35.79	
Min, Max	9.6, 79.9	10.2, 78.8	10.8, 90.0	1.3, 89.6	
C5D1 CFB					
n	15	33	47	85	
LS Mean (StdErr) [2]	-11.70 (3.390)	-11.03 (2.336)	-7.36 (2.501)	-16.43 (2.037)	
95% CI [2]	-18.54, -4.87	-15.74, -6.32	-12.30, -2.41	-20.46, -12.40	
Difference (95% CI) in CFB [2]		0.67 (-7.02, 8.36)		-9.08 (-14.45, -3.70)	
p-value [3]		0.861		0.001	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. CxD1 score is defined as the 14-day average of TSS prior to CxD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to CxD1 visit, the CxD1 score is considered as missing for the patient. Patients with high-dose steroid use within 7 days before CxD1, or greater than 14 consecutive days at any point from C1D1 to C7D1, the CxD1 score will be set to missing and will be excluded from the ANCOVA analysis.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.1.2.2.2a
Summary of Change from Baseline in TSS of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	15	32	45	83	
Mean (StdDev)	45.22 (21.267)	34.47 (15.823)	42.02 (18.189)	36.26 (21.656)	
Median	41.50	32.98	38.86	35.70	
Min, Max	13.0, 82.5	11.1, 81.9	9.4, 83.4	1.5, 100.6	
C6D1 CFB					
n	15	32	45	83	
LS Mean (StdErr) [2]	-12.70 (3.860)	-13.27 (2.738)	-8.52 (2.587)	-17.26 (2.151)	
95% CI [2]	-20.49, -4.92	-18.79, -7.75	-13.63, -3.40	-21.52, -13.00	
Difference (95% CI) in CFB [2]		-0.57 (-9.30, 8.17)		-8.75 (-14.37, -3.13)	
p-value [3]		0.896		0.003	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. CxD1 score is defined as the 14-day average of TSS prior to CxD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to CxD1 visit, the CxD1 score is considered as missing for the patient. Patients with high-dose steroid use within 7 days before CxD1, or greater than 14 consecutive days at any point from C1D1 to C7D1, the CxD1 score will be set to missing and will be excluded from the ANCOVA analysis.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.1.2.2.2a
Summary of Change from Baseline in TSS of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	15	33	46	79	
Mean (StdDev)	45.10 (22.581)	34.25 (15.410)	43.83 (19.860)	35.25 (22.018)	
Median	42.71	32.36	39.15	35.00	
Min, Max	10.5, 86.1	12.6, 80.9	5.5, 85.6	0.9, 103.5	
C7D1 CFB					
n	15	33	46	79	
LS Mean (StdErr) [2]	-12.54 (4.032)	-12.91 (2.778)	-8.44 (2.645)	-18.67 (2.190)	
95% CI [2]	-20.67, -4.41	-18.51, -7.31	-13.68, -3.20	-23.00, -14.33	
Difference (95% CI) in CFB [2]		-0.37 (-9.51, 8.78)		-10.23 (-15.98, -4.47)	
Hedges'G (95% CI) in CFB		-0.02 (-0.65, 0.60)		-0.54 (-0.92, -0.17)	
p-value [3]		0.936		<0.001	
					0.077

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. CxD1 score is defined as the 14-day average of TSS prior to CxD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to CxD1 visit, the CxD1 score is considered as missing for the patient. Patients with high-dose steroid use within 7 days before CxD1, or greater than 14 consecutive days at any point from C1D1 to C7D1, the CxD1 score will be set to missing and will be excluded from the ANCOVA analysis.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.1.2.2.3a
Summary of Change from Baseline in TSS of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	32	52	35	71	
Mean (StdDev)	55.10 (19.665)	53.88 (18.172)	53.68 (18.015)	52.91 (16.937)	
Median	49.07	48.92	47.79	49.62	
Min, Max	28.9, 104.4	28.6, 102.7	31.0, 87.3	29.3, 98.4	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. CxD1 score is defined as the 14-day average of TSS prior to CxD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to CxD1 visit, the CxD1 score is considered as missing for the patient. Patients with high-dose steroid use within 7 days before CxD1, or greater than 14 consecutive days at any point from C1D1 to C7D1, the CxD1 score will be set to missing and will be excluded from the ANCOVA analysis.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.1.2.2.3a
Summary of Change from Baseline in TSS of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	31	51	35	64	
Mean (StdDev)	48.43 (20.265)	46.86 (17.402)	48.22 (17.843)	43.88 (18.713)	
Median	42.85	42.07	43.79	40.36	
Min, Max	25.4, 98.9	21.8, 92.3	22.6, 81.4	13.8, 89.6	
C2D1 CFB					
n	31	51	35	64	
LS Mean (StdErr) [2]	-8.10 (1.517)	-8.17 (1.308)	-4.22 (1.722)	-7.95 (1.360)	
95% CI [2]	-11.12, -5.08	-10.77, -5.56	-7.64, -0.80	-10.65, -5.25	
Difference (95% CI) in CFB [2]		-0.07 (-3.49, 3.36)		-3.73 (-7.51, 0.05)	
p-value [3]		0.969		0.053	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. CxD1 score is defined as the 14-day average of TSS prior to CxD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to CxD1 visit, the CxD1 score is considered as missing for the patient. Patients with high-dose steroid use within 7 days before CxD1, or greater than 14 consecutive days at any point from C1D1 to C7D1, the CxD1 score will be set to missing and will be excluded from the ANCOVA analysis.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.1.2.2.3a
Summary of Change from Baseline in TSS of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	32	50	35	66	
Mean (StdDev)	47.09 (20.043)	42.25 (17.753)	44.52 (18.459)	40.08 (19.672)	
Median	43.46	41.16	41.00	39.36	
Min, Max	14.8, 93.8	11.2, 91.9	13.2, 78.4	8.9, 86.6	
C3D1 CFB					
n	32	50	35	66	
LS Mean (StdErr) [2]	-8.60 (2.063)	-12.18 (1.795)	-7.15 (2.349)	-11.27 (1.809)	
95% CI [2]	-12.71, -4.50	-15.76, -8.61	-11.82, -2.49	-14.86, -7.68	
Difference (95% CI) in CFB [2]		-3.58 (-8.24, 1.08)		-4.12 (-9.26, 1.03)	
p-value [3]		0.130		0.116	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. CxD1 score is defined as the 14-day average of TSS prior to CxD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to CxD1 visit, the CxD1 score is considered as missing for the patient. Patients with high-dose steroid use within 7 days before CxD1, or greater than 14 consecutive days at any point from C1D1 to C7D1, the CxD1 score will be set to missing and will be excluded from the ANCOVA analysis.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
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Table 35.2.1.2.2.3a
Summary of Change from Baseline in TSS of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	30	50	34	65	
Mean (StdDev)	45.57 (20.923)	39.57 (18.867)	45.73 (18.887)	38.86 (20.336)	
Median	39.39	39.36	42.61	36.64	
Min, Max	12.5, 90.0	4.1, 92.2	12.3, 83.5	4.9, 92.0	
C4D1 CFB					
n	30	50	34	65	
LS Mean (StdErr) [2]	-11.43 (2.686)	-15.29 (2.247)	-5.94 (2.602)	-12.67 (2.009)	
95% CI [2]	-16.78, -6.08	-19.77, -10.82	-11.10, -0.77	-16.66, -8.68	
Difference (95% CI) in CFB [2]		-3.86 (-9.78, 2.05)		-6.73 (-12.42, -1.04)	
p-value [3]		0.197		0.021	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. CxD1 score is defined as the 14-day average of TSS prior to CxD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to CxD1 visit, the CxD1 score is considered as missing for the patient. Patients with high-dose steroid use within 7 days before CxD1, or greater than 14 consecutive days at any point from C1D1 to C7D1, the CxD1 score will be set to missing and will be excluded from the ANCOVA analysis.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
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Table 35.2.1.2.2.3a
Summary of Change from Baseline in TSS of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	29	51	33	67	
Mean (StdDev)	46.16 (23.230)	37.31 (18.545)	45.01 (17.083)	37.56 (20.595)	
Median	41.57	33.92	41.43	35.33	
Min, Max	9.6, 90.0	8.8, 89.6	14.9, 79.9	1.3, 84.6	
C5D1 CFB					
n	29	51	33	67	
LS Mean (StdErr) [2]	-11.07 (2.836)	-17.11 (2.275)	-6.15 (2.872)	-13.09 (2.166)	
95% CI [2]	-16.72, -5.42	-21.64, -12.58	-11.85, -0.45	-17.39, -8.79	
Difference (95% CI) in CFB [2]		-6.04 (-12.29, 0.21)		-6.94 (-13.21, -0.67)	
p-value [3]		0.058		0.030	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. CxD1 score is defined as the 14-day average of TSS prior to CxD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to CxD1 visit, the CxD1 score is considered as missing for the patient. Patients with high-dose steroid use within 7 days before CxD1, or greater than 14 consecutive days at any point from C1D1 to C7D1, the CxD1 score will be set to missing and will be excluded from the ANCOVA analysis.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
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Table 35.2.1.2.2.3a
Summary of Change from Baseline in TSS of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	28	49	32	66	
Mean (StdDev)	43.64 (21.583)	36.07 (18.630)	42.10 (16.451)	35.54 (21.349)	
Median	39.94	35.70	39.10	33.90	
Min, Max	10.2, 83.4	3.3, 93.4	9.4, 74.5	1.5, 100.6	
C6D1 CFB					
n	28	49	32	66	
LS Mean (StdErr) [2]	-12.43 (3.143)	-18.42 (2.596)	-7.70 (2.879)	-14.66 (2.193)	
95% CI [2]	-18.69, -6.16	-23.59, -13.25	-13.41, -1.98	-19.01, -10.30	
Difference (95% CI) in CFB [2]		-5.99 (-12.98, 1.00)		-6.96 (-13.23, -0.69)	
p-value [3]		0.092		0.030	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. CxD1 score is defined as the 14-day average of TSS prior to CxD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to CxD1 visit, the CxD1 score is considered as missing for the patient. Patients with high-dose steroid use within 7 days before CxD1, or greater than 14 consecutive days at any point from C1D1 to C7D1, the CxD1 score will be set to missing and will be excluded from the ANCOVA analysis.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
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Table 35.2.1.2.2.3a
Summary of Change from Baseline in TSS of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	29	47	32	65	
Mean (StdDev)	44.43 (24.092)	34.42 (18.514)	43.89 (16.704)	35.35 (21.523)	
Median	40.33	34.15	40.47	33.93	
Min, Max	5.5, 86.1	5.8, 93.6	16.3, 81.8	0.9, 103.5	
C7D1 CFB					
n	29	47	32	65	
LS Mean (StdErr) [2]	-12.92 (3.184)	-20.17 (2.652)	-6.68 (3.008)	-14.58 (2.236)	
95% CI [2]	-19.27, -6.57	-25.45, -14.88	-12.65, -0.70	-19.02, -10.14	
Difference (95% CI) in CFB [2]		-7.25 (-14.38, -0.11)		-7.90 (-14.45, -1.35)	
Hedges'G (95% CI) in CFB		-0.40 (-0.89, 0.06)		-0.44 (-0.89, -0.02)	
p-value [3]		0.047		0.019	
					0.962

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. CxD1 score is defined as the 14-day average of TSS prior to CxD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to CxD1 visit, the CxD1 score is considered as missing for the patient. Patients with high-dose steroid use within 7 days before CxD1, or greater than 14 consecutive days at any point from C1D1 to C7D1, the CxD1 score will be set to missing and will be excluded from the ANCOVA analysis.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
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Table 35.2.1.2.2.4a
Summary of Change from Baseline in TSS of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. CxD1 score is defined as the 14-day average of TSS prior to CxD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to CxD1 visit, the CxD1 score is considered as missing for the patient. Patients with high-dose steroid use within 7 days before CxD1, or greater than 14 consecutive days at any point from C1D1 to C7D1, the CxD1 score will be set to missing and will be excluded from the ANCOVA analysis.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
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Table 35.2.1.2.2.4a
Summary of Change from Baseline in TSS of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. CxD1 score is defined as the 14-day average of TSS prior to CxD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to CxD1 visit, the CxD1 score is considered as missing for the patient. Patients with high-dose steroid use within 7 days before CxD1, or greater than 14 consecutive days at any point from C1D1 to C7D1, the CxD1 score will be set to missing and will be excluded from the ANCOVA analysis.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
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Table 35.2.1.2.2.4a
Summary of Change from Baseline in TSS of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. CxD1 score is defined as the 14-day average of TSS prior to CxD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to CxD1 visit, the CxD1 score is considered as missing for the patient. Patients with high-dose steroid use within 7 days before CxD1, or greater than 14 consecutive days at any point from C1D1 to C7D1, the CxD1 score will be set to missing and will be excluded from the ANCOVA analysis.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
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Table 35.2.1.2.2.4a
Summary of Change from Baseline in TSS of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. CxD1 score is defined as the 14-day average of TSS prior to CxD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to CxD1 visit, the CxD1 score is considered as missing for the patient. Patients with high-dose steroid use within 7 days before CxD1, or greater than 14 consecutive days at any point from C1D1 to C7D1, the CxD1 score will be set to missing and will be excluded from the ANCOVA analysis.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tss-sum-g-pp-cou-a.sas Date: 14:35/07AUG2023

Table 35.2.1.2.2.4a
Summary of Change from Baseline in TSS of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. CxD1 score is defined as the 14-day average of TSS prior to CxD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to CxD1 visit, the CxD1 score is considered as missing for the patient. Patients with high-dose steroid use within 7 days before CxD1, or greater than 14 consecutive days at any point from C1D1 to C7D1, the CxD1 score will be set to missing and will be excluded from the ANCOVA analysis.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tss-sum-g-pp-cou-a.sas Date: 14:35/07AUG2023

Table 35.2.1.2.2.5a
Summary of Change from Baseline in TSS of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	22	37	45	86	
Mean (StdDev)	36.11 (3.755)	35.41 (3.603)	63.28 (16.409)	61.02 (15.147)	
Median	36.62	35.92	60.00	56.70	
Min, Max	28.9, 41.3	28.6, 41.4	42.1, 104.4	42.4, 102.7	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. CxD1 score is defined as the 14-day average of TSS prior to CxD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to CxD1 visit, the CxD1 score is considered as missing for the patient. Patients with high-dose steroid use within 7 days before CxD1, or greater than 14 consecutive days at any point from C1D1 to C7D1, the CxD1 score will be set to missing and will be excluded from the ANCOVA analysis.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tss-sum-g-pp-ism-a.sas Date: 14:36/07AUG2023

Table 35.2.1.2.2.5a
Summary of Change from Baseline in TSS of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	22	34	44	81	
Mean (StdDev)	31.96 (6.306)	29.65 (6.827)	56.50 (17.708)	51.73 (17.410)	
Median	31.29	29.35	52.57	47.46	
Min, Max	22.6, 46.1	13.8, 46.4	25.4, 98.9	17.4, 92.3	
C2D1 CFB					
n	22	34	44	81	
LS Mean (StdErr) [2]	-4.85 (1.446)	-6.02 (1.073)	-7.56 (1.528)	-9.94 (1.265)	
95% CI [2]	-7.75, -1.95	-8.17, -3.86	-10.58, -4.54	-12.44, -7.44	
Difference (95% CI) in CFB [2]		-1.17 (-4.35, 2.01)		-2.38 (-5.92, 1.16)	
p-value [3]		0.465		0.185	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. CxD1 score is defined as the 14-day average of TSS prior to CxD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to CxD1 visit, the CxD1 score is considered as missing for the patient. Patients with high-dose steroid use within 7 days before CxD1, or greater than 14 consecutive days at any point from C1D1 to C7D1, the CxD1 score will be set to missing and will be excluded from the ANCOVA analysis.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tss-sum-g-pp-ism-a.sas Date: 14:36/07AUG2023

Table 35.2.1.2.2.5a
Summary of Change from Baseline in TSS of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	22	34	45	82	
Mean (StdDev)	30.89 (8.889)	27.52 (10.307)	53.02 (18.621)	46.61 (18.749)	
Median	29.50	26.62	51.79	45.36	
Min, Max	13.2, 46.4	10.6, 59.4	14.8, 93.8	8.9, 91.9	
C3D1 CFB					
n	22	34	45	82	
LS Mean (StdErr) [2]	-6.54 (2.289)	-8.50 (1.699)	-10.24 (1.985)	-14.71 (1.607)	
95% CI [2]	-11.13, -1.95	-11.91, -5.09	-14.17, -6.31	-17.89, -11.53	
Difference (95% CI) in CFB [2]		-1.96 (-6.99, 3.07)		-4.47 (-9.06, 0.12)	
p-value [3]		0.438		0.056	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. CxD1 score is defined as the 14-day average of TSS prior to CxD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to CxD1 visit, the CxD1 score is considered as missing for the patient. Patients with high-dose steroid use within 7 days before CxD1, or greater than 14 consecutive days at any point from C1D1 to C7D1, the CxD1 score will be set to missing and will be excluded from the ANCOVA analysis.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
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Table 35.2.1.2.2.5a
Summary of Change from Baseline in TSS of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	20	32	44	83	
Mean (StdDev)	30.67 (9.057)	25.49 (10.400)	52.46 (19.517)	44.44 (19.840)	
Median	28.96	24.50	50.21	42.93	
Min, Max	12.3, 48.4	10.0, 43.5	12.5, 90.0	4.1, 92.2	
C4D1 CFB					
n	20	32	44	83	
LS Mean (StdErr) [2]	-4.60 (2.408)	-9.35 (1.760)	-11.50 (2.390)	-17.35 (1.899)	
95% CI [2]	-9.44, 0.24	-12.89, -5.81	-16.23, -6.77	-21.10, -13.59	
Difference (95% CI) in CFB [2]		-4.75 (-10.11, 0.62)		-5.85 (-11.29, -0.41)	
p-value [3]		0.082		0.035	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. CxD1 score is defined as the 14-day average of TSS prior to CxD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to CxD1 visit, the CxD1 score is considered as missing for the patient. Patients with high-dose steroid use within 7 days before CxD1, or greater than 14 consecutive days at any point from C1D1 to C7D1, the CxD1 score will be set to missing and will be excluded from the ANCOVA analysis.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
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Table 35.2.1.2.2.5a
Summary of Change from Baseline in TSS of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	35	43	83	
Mean (StdDev)	29.64 (9.240)	25.51 (11.243)	52.58 (19.515)	42.49 (20.303)	
Median	29.69	25.89	52.46	40.27	
Min, Max	10.8, 41.6	7.1, 49.5	9.6, 90.0	1.3, 89.6	
C5D1 CFB					
n	19	35	43	83	
LS Mean (StdErr) [2]	-5.16 (2.609)	-9.35 (1.810)	-11.65 (2.589)	-19.44 (2.042)	
95% CI [2]	-10.40, 0.08	-12.99, -5.72	-16.78, -6.53	-23.48, -15.39	
Difference (95% CI) in CFB [2]		-4.19 (-9.96, 1.57)		-7.79 (-13.68, -1.89)	
p-value [3]		0.150		0.010	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. CxD1 score is defined as the 14-day average of TSS prior to CxD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to CxD1 visit, the CxD1 score is considered as missing for the patient. Patients with high-dose steroid use within 7 days before CxD1, or greater than 14 consecutive days at any point from C1D1 to C7D1, the CxD1 score will be set to missing and will be excluded from the ANCOVA analysis.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
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Table 35.2.1.2.2.5a
Summary of Change from Baseline in TSS of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	20	34	40	81	
Mean (StdDev)	31.66 (10.212)	24.11 (11.442)	48.40 (19.798)	40.66 (21.040)	
Median	31.90	23.17	47.36	39.93	
Min, Max	9.4, 51.3	5.6, 56.1	10.2, 83.4	1.5, 100.6	
C6D1 CFB					
n	20	34	40	81	
LS Mean (StdErr) [2]	-3.50 (2.697)	-11.10 (1.991)	-14.69 (2.783)	-20.98 (2.156)	
95% CI [2]	-8.92, 1.91	-15.10, -7.10	-20.20, -9.17	-25.24, -16.71	
Difference (95% CI) in CFB [2]		-7.60 (-13.44, -1.75)		-6.29 (-12.66, 0.08)	
p-value [3]		0.012		0.053	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. CxD1 score is defined as the 14-day average of TSS prior to CxD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to CxD1 visit, the CxD1 score is considered as missing for the patient. Patients with high-dose steroid use within 7 days before CxD1, or greater than 14 consecutive days at any point from C1D1 to C7D1, the CxD1 score will be set to missing and will be excluded from the ANCOVA analysis.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
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Table 35.2.1.2.2.5a
Summary of Change from Baseline in TSS of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	19	34	42	78	
Mean (StdDev)	30.88 (9.098)	23.67 (11.816)	50.14 (21.278)	39.88 (21.201)	
Median	30.50	23.67	51.75	39.87	
Min, Max	16.3, 45.1	6.4, 51.9	5.5, 86.1	0.9, 103.5	
C7D1 CFB					
n	19	34	42	78	
LS Mean (StdErr) [2]	-4.67 (2.671)	-11.43 (1.864)	-13.90 (2.849)	-21.92 (2.289)	
95% CI [2]	-10.04, 0.69	-15.17, -7.68	-19.55, -8.26	-26.46, -17.39	
Difference (95% CI) in CFB [2]		-6.75 (-12.69, -0.82)		-8.02 (-14.56, -1.47)	
Hedges'G (95% CI) in CFB		-0.60 (-1.21, -0.04)		-0.41 (-0.80, -0.03)	
p-value [3]		0.027		0.017	
					0.780

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. CxD1 score is defined as the 14-day average of TSS prior to CxD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to CxD1 visit, the CxD1 score is considered as missing for the patient. Patients with high-dose steroid use within 7 days before CxD1, or greater than 14 consecutive days at any point from C1D1 to C7D1, the CxD1 score will be set to missing and will be excluded from the ANCOVA analysis.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
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Table 35.2.1.2.2.7a
Summary of Change from Baseline in TSS of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	63	114	4	9	
Mean (StdDev)	54.57 (18.519)	52.69 (17.396)	51.13 (24.146)	61.22 (16.389)	
Median	48.43	49.07	43.50	59.46	
Min, Max	28.9, 104.4	28.6, 102.7	32.2, 85.3	39.2, 85.9	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. CxD1 score is defined as the 14-day average of TSS prior to CxD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to CxD1 visit, the CxD1 score is considered as missing for the patient. Patients with high-dose steroid use within 7 days before CxD1, or greater than 14 consecutive days at any point from C1D1 to C7D1, the CxD1 score will be set to missing and will be excluded from the ANCOVA analysis.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
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Table 35.2.1.2.2.7a
Summary of Change from Baseline in TSS of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	62	106	4	9	
Mean (StdDev)	48.42 (19.221)	44.44 (17.831)	46.79 (14.127)	54.19 (20.258)	
Median	43.36	40.57	49.79	51.14	
Min, Max	22.6, 98.9	13.8, 92.3	27.4, 60.1	19.1, 80.6	
C2D1 CFB					
n	62	106	4	9	
LS Mean (StdErr) [2]	-6.14 (1.184)	-8.21 (0.976)	0.18 (8.135)	-2.47 (6.446)	
95% CI [2]	-8.47, -3.80	-10.14, -6.29	-18.22, 18.58	-17.06, 12.11	
Difference (95% CI) in CFB [2]		-2.08 (-4.72, 0.56)		-2.65 (-18.53, 13.22)	
p-value [3]		0.122		0.714	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. CxD1 score is defined as the 14-day average of TSS prior to CxD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to CxD1 visit, the CxD1 score is considered as missing for the patient. Patients with high-dose steroid use within 7 days before CxD1, or greater than 14 consecutive days at any point from C1D1 to C7D1, the CxD1 score will be set to missing and will be excluded from the ANCOVA analysis.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
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Table 35.2.1.2.2.7a
Summary of Change from Baseline in TSS of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	63	107	4	9	
Mean (StdDev)	45.74 (19.440)	40.09 (18.444)	46.02 (15.474)	52.06 (20.861)	
Median	42.21	38.78	50.25	49.50	
Min, Max	13.2, 93.8	8.9, 91.9	24.2, 59.4	10.6, 78.1	
C3D1 CFB					
n	63	107	4	9	
LS Mean (StdErr) [2]	-7.88 (1.608)	-11.90 (1.309)	0.56 (9.800)	-4.27 (7.766)	
95% CI [2]	-11.05, -4.70	-14.48, -9.31	-21.61, 22.73	-21.84, 13.30	
Difference (95% CI) in CFB [2]		-4.02 (-7.60, -0.43)		-4.83 (-23.96, 14.29)	
p-value [3]		0.028		0.582	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. CxD1 score is defined as the 14-day average of TSS prior to CxD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to CxD1 visit, the CxD1 score is considered as missing for the patient. Patients with high-dose steroid use within 7 days before CxD1, or greater than 14 consecutive days at any point from C1D1 to C7D1, the CxD1 score will be set to missing and will be excluded from the ANCOVA analysis.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tss-sum-g-pp-ecog-a.sas Date: 14:37/07AUG2023

Table 35.2.1.2.2.7a
Summary of Change from Baseline in TSS of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	60	106	4	9	
Mean (StdDev)	45.82 (20.223)	38.28 (19.266)	43.23 (10.227)	49.70 (21.993)	
Median	39.14	37.22	47.18	47.36	
Min, Max	12.3, 90.0	4.1, 92.2	28.1, 50.4	10.0, 78.4	
C4D1 CFB					
n	60	106	4	9	
LS Mean (StdErr) [2]	-8.20 (1.915)	-13.90 (1.531)	-1.42 (12.035)	-4.39 (9.537)	
95% CI [2]	-11.98, -4.42	-16.93, -10.88	-28.64, 25.81	-25.97, 17.18	
Difference (95% CI) in CFB [2]		-5.70 (-9.92, -1.48)		-2.98 (-26.46, 20.51)	
p-value [3]		0.008		0.781	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. CxD1 score is defined as the 14-day average of TSS prior to CxD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to CxD1 visit, the CxD1 score is considered as missing for the patient. Patients with high-dose steroid use within 7 days before CxD1, or greater than 14 consecutive days at any point from C1D1 to C7D1, the CxD1 score will be set to missing and will be excluded from the ANCOVA analysis.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
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Table 35.2.1.2.2.7a
Summary of Change from Baseline in TSS of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	58	109	4	9	
Mean (StdDev)	45.94 (20.406)	36.16 (18.512)	39.88 (14.101)	53.09 (26.925)	
Median	41.33	34.15	43.61	56.14	
Min, Max	9.6, 90.0	1.3, 89.6	19.9, 52.5	7.1, 82.4	
C5D1 CFB					
n	58	109	4	9	
LS Mean (StdErr) [2]	-8.01 (1.967)	-15.45 (1.519)	2.29 (17.040)	2.89 (13.502)	
95% CI [2]	-11.89, -4.12	-18.45, -12.45	-36.26, 40.84	-27.66, 33.43	
Difference (95% CI) in CFB [2]		-7.44 (-11.76, -3.12)		0.60 (-32.66, 33.85)	
p-value [3]		<0.001		0.968	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. CxD1 score is defined as the 14-day average of TSS prior to CxD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to CxD1 visit, the CxD1 score is considered as missing for the patient. Patients with high-dose steroid use within 7 days before CxD1, or greater than 14 consecutive days at any point from C1D1 to C7D1, the CxD1 score will be set to missing and will be excluded from the ANCOVA analysis.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
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Table 35.2.1.2.2.7a
Summary of Change from Baseline in TSS of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	56	106	4	9	
Mean (StdDev)	42.87 (19.436)	34.76 (19.562)	42.16 (8.644)	47.63 (24.340)	
Median	38.89	32.98	45.25	43.50	
Min, Max	9.4, 83.4	1.5, 100.6	29.4, 48.7	5.6, 80.0	
C6D1 CFB					
n	56	106	4	9	
LS Mean (StdErr) [2]	-9.67 (2.176)	-16.66 (1.716)	4.95 (12.522)	-0.74 (9.922)	
95% CI [2]	-13.97, -5.38	-20.05, -13.27	-23.37, 33.28	-23.18, 21.71	
Difference (95% CI) in CFB [2]		-6.99 (-11.79, -2.19)		-5.69 (-30.12, 18.75)	
p-value [3]		0.005		0.611	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. CxD1 score is defined as the 14-day average of TSS prior to CxD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to CxD1 visit, the CxD1 score is considered as missing for the patient. Patients with high-dose steroid use within 7 days before CxD1, or greater than 14 consecutive days at any point from C1D1 to C7D1, the CxD1 score will be set to missing and will be excluded from the ANCOVA analysis.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
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Table 35.2.1.2.2.7a
Summary of Change from Baseline in TSS of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	58	103	3	9	
Mean (StdDev)	44.04 (20.883)	34.01 (19.535)	46.14 (4.272)	45.76 (25.903)	
Median	39.15	33.43	44.79	37.93	
Min, Max	5.5, 86.1	0.9, 103.5	42.7, 50.9	6.4, 81.5	
C7D1 CFB					
n	58	103	3	9	
LS Mean (StdErr) [2]	-9.40 (2.204)	-17.27 (1.738)	3.68 (16.246)	-2.51 (11.821)	
95% CI [2]	-13.75, -5.04	-20.71, -13.84	-33.78, 41.14	-29.77, 24.75	
Difference (95% CI) in CFB [2]		-7.88 (-12.78, -2.97)		-6.19 (-37.67, 25.28)	
Hedges'G (95% CI) in CFB		-0.45 (-0.79, -0.13)		-0.17 (-1.70, 1.28)	
p-value [3]		0.002		0.662	
					0.650

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. CxD1 score is defined as the 14-day average of TSS prior to CxD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to CxD1 visit, the CxD1 score is considered as missing for the patient. Patients with high-dose steroid use within 7 days before CxD1, or greater than 14 consecutive days at any point from C1D1 to C7D1, the CxD1 score will be set to missing and will be excluded from the ANCOVA analysis.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
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Table 35.2.1.2.2.8a
Summary of Change from Baseline in TSS of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	64	113	
Mean (StdDev)	52.14 (17.302)	63.12 (19.595)	54.46 (18.874)	52.45 (17.021)	
Median	48.43	61.04	48.73	49.07	
Min, Max	37.0, 71.0	28.6, 95.5	28.9, 104.4	29.3, 102.7	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. CxD1 score is defined as the 14-day average of TSS prior to CxD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to CxD1 visit, the CxD1 score is considered as missing for the patient. Patients with high-dose steroid use within 7 days before CxD1, or greater than 14 consecutive days at any point from C1D1 to C7D1, the CxD1 score will be set to missing and will be excluded from the ANCOVA analysis.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
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Table 35.2.1.2.2.8a
Summary of Change from Baseline in TSS of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	9	63	106	
Mean (StdDev)	47.67 (18.131)	55.76 (18.484)	48.35 (19.044)	44.30 (17.898)	
Median	40.50	58.29	43.79	40.57	
Min, Max	34.2, 68.3	28.1, 83.3	22.6, 98.9	13.8, 92.3	
C2D1 CFB					
n	3	9	63	106	
LS Mean (StdErr) [2]	-5.06 (3.013)	-9.49 (3.013)	-6.00 (1.232)	-8.00 (1.010)	
95% CI [2]	-12.01, 1.88	-16.44, -2.54	-8.43, -3.57	-10.00, -6.01	
Difference (95% CI) in CFB [2]		-4.43 (-12.62, 3.77)		-2.00 (-4.73, 0.73)	
p-value [3]		0.248		0.150	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. CxD1 score is defined as the 14-day average of TSS prior to CxD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to CxD1 visit, the CxD1 score is considered as missing for the patient. Patients with high-dose steroid use within 7 days before CxD1, or greater than 14 consecutive days at any point from C1D1 to C7D1, the CxD1 score will be set to missing and will be excluded from the ANCOVA analysis.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
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Table 35.2.1.2.2.8a
Summary of Change from Baseline in TSS of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	8	64	108	
Mean (StdDev)	44.76 (17.868)	49.75 (16.996)	45.80 (19.317)	40.37 (18.858)	
Median	41.00	48.64	42.93	39.07	
Min, Max	29.1, 64.2	29.1, 80.5	13.2, 93.8	8.9, 91.9	
C3D1 CFB					
n	3	8	64	108	
LS Mean (StdErr) [2]	-6.15 (6.354)	-12.22 (5.611)	-7.80 (1.647)	-11.49 (1.343)	
95% CI [2]	-21.18, 8.87	-25.49, 1.05	-11.05, -4.55	-14.14, -8.84	
Difference (95% CI) in CFB [2]		-6.06 (-23.33, 11.21)		-3.69 (-7.33, -0.05)	
p-value [3]		0.434		0.047	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. CxD1 score is defined as the 14-day average of TSS prior to CxD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to CxD1 visit, the CxD1 score is considered as missing for the patient. Patients with high-dose steroid use within 7 days before CxD1, or greater than 14 consecutive days at any point from C1D1 to C7D1, the CxD1 score will be set to missing and will be excluded from the ANCOVA analysis.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
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Table 35.2.1.2.2.8a
Summary of Change from Baseline in TSS of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	3	9	61	106	
Mean (StdDev)	42.41 (21.592)	42.98 (17.198)	45.81 (19.791)	38.85 (19.861)	
Median	31.07	42.93	40.86	37.64	
Min, Max	28.8, 67.3	19.6, 80.2	12.3, 90.0	4.1, 92.2	
C4D1 CFB					
n	3	9	61	106	
LS Mean (StdErr) [2]	-10.23 (8.206)	-21.07 (7.254)	-7.92 (1.941)	-12.95 (1.554)	
95% CI [2]	-29.16, 8.69	-37.80, -4.35	-11.75, -4.08	-16.02, -9.88	
Difference (95% CI) in CFB [2]		-10.84 (-32.52, 10.84)		-5.03 (-9.28, -0.78)	
p-value [3]		0.282		0.021	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. CxD1 score is defined as the 14-day average of TSS prior to CxD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to CxD1 visit, the CxD1 score is considered as missing for the patient. Patients with high-dose steroid use within 7 days before CxD1, or greater than 14 consecutive days at any point from C1D1 to C7D1, the CxD1 score will be set to missing and will be excluded from the ANCOVA analysis.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
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Table 35.2.1.2.2.8a
Summary of Change from Baseline in TSS of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	9	59	109	
Mean (StdDev)	39.96 (20.546)	38.74 (16.914)	45.83 (20.140)	37.34 (19.928)	
Median	29.69	38.15	41.57	34.29	
Min, Max	26.6, 63.6	18.6, 78.3	9.6, 90.0	1.3, 89.6	
C5D1 CFB					
n	3	9	59	109	
LS Mean (StdErr) [2]	-13.45 (7.764)	-26.29 (6.862)	-7.74 (2.086)	-13.81 (1.617)	
95% CI [2]	-31.35, 4.45	-42.12, -10.47	-11.86, -3.62	-17.00, -10.61	
Difference (95% CI) in CFB [2]		-12.84 (-33.35, 7.67)		-6.06 (-10.61, -1.51)	
p-value [3]		0.187		0.009	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. CxD1 score is defined as the 14-day average of TSS prior to CxD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to CxD1 visit, the CxD1 score is considered as missing for the patient. Patients with high-dose steroid use within 7 days before CxD1, or greater than 14 consecutive days at any point from C1D1 to C7D1, the CxD1 score will be set to missing and will be excluded from the ANCOVA analysis.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
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Table 35.2.1.2.2.8a
Summary of Change from Baseline in TSS of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	57	106	
Mean (StdDev)	38.27 (22.432)	36.69 (17.836)	43.06 (18.866)	35.69 (20.410)	
Median	26.07	38.71	39.29	34.75	
Min, Max	24.6, 64.2	14.8, 76.4	9.4, 83.4	1.5, 100.6	
C6D1 CFB					
n	3	9	57	106	
LS Mean (StdErr) [2]	-16.19 (9.348)	-30.36 (8.263)	-8.90 (2.178)	-15.04 (1.723)	
95% CI [2]	-37.75, 5.36	-49.42, -11.31	-13.20, -4.60	-18.44, -11.64	
Difference (95% CI) in CFB [2]		-14.17 (-38.86, 10.53)		-6.14 (-10.90, -1.37)	
p-value [3]		0.222		0.012	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. CxD1 score is defined as the 14-day average of TSS prior to CxD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to CxD1 visit, the CxD1 score is considered as missing for the patient. Patients with high-dose steroid use within 7 days before CxD1, or greater than 14 consecutive days at any point from C1D1 to C7D1, the CxD1 score will be set to missing and will be excluded from the ANCOVA analysis.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tss-sum-g-pp-thpy-a.sas Date: 14:38/07AUG2023

Table 35.2.1.2.2.8a
Summary of Change from Baseline in TSS of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	9	58	103	
Mean (StdDev)	39.75 (18.354)	37.12 (18.683)	44.37 (20.593)	34.77 (20.436)	
Median	30.86	36.79	40.60	33.93	
Min, Max	27.5, 60.9	14.1, 78.6	5.5, 86.1	0.9, 103.5	
C7D1 CFB					
n	3	9	58	103	
LS Mean (StdErr) [2]	-14.26 (9.954)	-29.09 (8.798)	-8.79 (2.245)	-15.88 (1.761)	
95% CI [2]	-37.22, 8.69	-49.38, -8.80	-13.23, -4.36	-19.36, -12.40	
Difference (95% CI) in CFB [2]		-14.83 (-41.12, 11.47)		-7.09 (-12.03, -2.14)	
Hedges'G (95% CI) in CFB		-0.55 (-2.20, 0.82)		-0.40 (-0.73, -0.08)	
p-value [3]		0.230		0.005	
					0.601

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. CxD1 score is defined as the 14-day average of TSS prior to CxD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to CxD1 visit, the CxD1 score is considered as missing for the patient. Patients with high-dose steroid use within 7 days before CxD1, or greater than 14 consecutive days at any point from C1D1 to C7D1, the CxD1 score will be set to missing and will be excluded from the ANCOVA analysis.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
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Table 35.2.2.2.2.1a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	56	117	11	6	
Mean (StdDev)	11.97 (6.545)	10.44 (6.058)	5.44 (5.041)	10.20 (6.359)	
Median	10.42	9.50	4.00	10.18	
Min, Max	0.1, 28.0	0.1, 26.8	0.0, 15.3	1.9, 18.1	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.1a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	56	113	11	6	
Mean (StdDev)	9.75 (6.412)	8.54 (5.922)	4.21 (3.281)	7.40 (4.483)	
Median	8.35	7.36	3.50	8.31	
Min, Max	0.5, 26.4	0.0, 24.0	0.0, 9.8	1.6, 11.9	
C2D1 CFB					
n	56	113	11	6	
LS Mean (StdErr) [2]	-1.89 (0.437)	-1.65 (0.330)	-4.09 (1.210)	-6.33 (1.764)	
95% CI [2]	-2.75, -1.03	-2.30, -1.00	-6.71, -1.48	-10.14, -2.52	
Difference (95% CI) in CFB [2]		0.24 (-0.71, 1.18)		-2.24 (-5.21, 0.72)	
p-value [3]		0.620		0.127	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.1a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	56	111	11	6	
Mean (StdDev)	8.87 (6.439)	7.69 (5.678)	4.61 (4.241)	4.62 (2.505)	
Median	8.08	7.50	3.43	4.86	
Min, Max	0.2, 23.9	0.0, 24.0	0.0, 12.1	0.4, 7.4	
C3D1 CFB					
n	56	111	11	6	
LS Mean (StdErr) [2]	-2.70 (0.559)	-2.41 (0.422)	-3.82 (1.840)	-9.20 (2.682)	
95% CI [2]	-3.80, -1.59	-3.25, -1.58	-7.79, 0.16	-14.99, -3.40	
Difference (95% CI) in CFB [2]		0.28 (-0.93, 1.50)		-5.38 (-9.89, -0.87)	
p-value [3]		0.645		0.023	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.1a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	54	111	10	6	
Mean (StdDev)	9.10 (6.375)	7.07 (5.773)	4.79 (3.460)	4.08 (2.930)	
Median	8.14	5.92	6.07	4.54	
Min, Max	0.0, 23.5	0.0, 24.8	0.0, 9.6	0.2, 7.5	
C4D1 CFB					
n	54	111	10	6	
LS Mean (StdErr) [2]	-2.71 (0.655)	-3.11 (0.486)	-3.70 (2.090)	-9.22 (3.022)	
95% CI [2]	-4.00, -1.42	-4.07, -2.15	-8.26, 0.85	-15.81, -2.64	
Difference (95% CI) in CFB [2]		-0.40 (-1.81, 1.01)		-5.52 (-10.66, -0.38)	
p-value [3]		0.575		0.037	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.1a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	54	113	9	6	
Mean (StdDev)	9.03 (6.096)	6.91 (5.930)	5.38 (3.880)	2.68 (2.246)	
Median	7.93	5.93	6.43	2.34	
Min, Max	0.0, 23.3	0.0, 25.0	0.0, 10.4	0.1, 6.4	
C5D1 CFB					
n	54	113	9	6	
LS Mean (StdErr) [2]	-2.77 (0.698)	-3.26 (0.510)	-3.67 (2.562)	-10.86 (3.665)	
95% CI [2]	-4.15, -1.40	-4.27, -2.25	-9.31, 1.96	-18.93, -2.79	
Difference (95% CI) in CFB [2]		-0.49 (-1.99, 1.02)		-7.18 (-13.50, -0.87)	
p-value [3]		0.523		0.029	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.1a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	52	112	10	6	
Mean (StdDev)	8.15 (6.110)	6.41 (5.751)	3.84 (2.936)	3.40 (2.937)	
Median	7.02	5.15	3.54	2.96	
Min, Max	0.1, 20.8	0.0, 25.5	0.0, 8.1	0.5, 7.0	
C6D1 CFB					
n	52	112	10	6	
LS Mean (StdErr) [2]	-3.22 (0.712)	-3.60 (0.514)	-4.35 (2.166)	-9.25 (3.132)	
95% CI [2]	-4.63, -1.82	-4.62, -2.59	-9.07, 0.37	-16.08, -2.43	
Difference (95% CI) in CFB [2]		-0.38 (-1.92, 1.16)		-4.90 (-10.23, 0.42)	
p-value [3]		0.625		0.068	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.1a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	52	109	10	6	
Mean (StdDev)	8.35 (6.431)	6.43 (5.739)	4.42 (4.199)	3.18 (2.718)	
Median	6.95	5.14	4.00	2.75	
Min, Max	0.1, 22.9	0.0, 26.4	0.0, 11.1	0.4, 7.6	
C7D1 CFB					
n	52	109	10	6	
LS Mean (StdErr) [2]	-3.09 (0.749)	-3.50 (0.545)	-4.85 (2.065)	-11.76 (2.987)	
95% CI [2]	-4.57, -1.61	-4.58, -2.43	-9.35, -0.35	-18.26, -5.25	
Difference (95% CI) in CFB [2]		-0.41 (-2.03, 1.21)		-6.91 (-11.99, -1.83)	
Hedges'G (95% CI) in CFB		-0.07 (-0.41, 0.26)		-0.96 (-2.30, 0.06)	
p-value [3]		0.615		0.012	
					0.102

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.1a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	56	117	11	6	
Mean (StdDev)	17.43 (7.041)	16.31 (6.663)	20.54 (7.420)	17.92 (8.309)	
Median	18.07	16.17	20.71	20.18	
Min, Max	0.0, 30.0	1.9, 30.0	8.1, 30.0	6.6, 26.9	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.1a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	56	113	11	6	
Mean (StdDev)	15.83 (6.719)	13.76 (5.931)	18.67 (8.923)	12.57 (7.722)	
Median	16.41	13.21	18.86	11.21	
Min, Max	0.0, 29.2	0.0, 28.5	5.6, 29.8	4.6, 25.9	
C2D1 CFB					
n	56	113	11	6	
LS Mean (StdErr) [2]	-1.52 (0.504)	-2.60 (0.380)	-1.21 (2.225)	-5.45 (3.243)	
95% CI [2]	-2.52, -0.53	-3.35, -1.85	-6.01, 3.60	-12.46, 1.56	
Difference (95% CI) in CFB [2]		-1.08 (-2.17, 0.01)		-4.24 (-9.69, 1.21)	
p-value [3]		0.053		0.117	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.1a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	56	111	11	6	
Mean (StdDev)	15.36 (7.085)	12.13 (5.997)	17.88 (8.604)	10.32 (7.808)	
Median	16.21	11.36	21.00	9.07	
Min, Max	0.0, 29.4	0.1, 28.1	6.0, 28.6	2.4, 24.1	
C3D1 CFB					
n	56	111	11	6	
LS Mean (StdErr) [2]	-1.56 (0.649)	-3.90 (0.491)	-2.32 (2.438)	-7.77 (3.554)	
95% CI [2]	-2.84, -0.28	-4.87, -2.93	-7.59, 2.95	-15.45, -0.09	
Difference (95% CI) in CFB [2]		-2.34 (-3.75, -0.93)		-5.45 (-11.42, 0.52)	
p-value [3]		0.001		0.070	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.1a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	54	111	10	6	
Mean (StdDev)	15.07 (7.195)	11.50 (6.057)	18.24 (8.738)	8.60 (8.476)	
Median	15.96	10.86	21.00	5.47	
Min, Max	0.0, 29.7	0.0, 28.6	6.9, 28.6	1.7, 24.0	
C4D1 CFB					
n	54	111	10	6	
LS Mean (StdErr) [2]	-1.95 (0.718)	-4.58 (0.534)	-1.80 (3.131)	-8.41 (4.528)	
95% CI [2]	-3.37, -0.53	-5.63, -3.52	-8.62, 5.02	-18.27, 1.46	
Difference (95% CI) in CFB [2]		-2.63 (-4.17, -1.08)		-6.61 (-14.31, 1.09)	
p-value [3]		<0.001		0.086	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.1a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	54	113	9	6	
Mean (StdDev)	14.77 (7.183)	10.86 (5.933)	20.71 (7.229)	7.15 (8.480)	
Median	15.73	10.21	22.36	4.25	
Min, Max	0.0, 29.9	0.1, 28.5	9.8, 30.0	0.3, 23.2	
C5D1 CFB					
n	54	113	9	6	
LS Mean (StdErr) [2]	-2.28 (0.781)	-5.15 (0.571)	-0.64 (2.956)	-10.12 (4.228)	
95% CI [2]	-3.82, -0.73	-6.27, -4.02	-7.15, 5.86	-19.43, -0.81	
Difference (95% CI) in CFB [2]		-2.87 (-4.55, -1.19)		-9.48 (-16.77, -2.19)	
p-value [3]		<0.001		0.015	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.1a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	52	112	10	6	
Mean (StdDev)	14.84 (6.984)	10.49 (6.230)	18.69 (9.169)	6.79 (7.493)	
Median	15.55	9.99	21.29	4.75	
Min, Max	0.0, 29.8	0.1, 30.0	1.6, 30.0	0.9, 20.5	
C6D1 CFB					
n	52	112	10	6	
LS Mean (StdErr) [2]	-2.21 (0.864)	-5.50 (0.624)	-1.73 (2.983)	-10.76 (4.314)	
95% CI [2]	-3.91, -0.50	-6.73, -4.27	-8.23, 4.77	-20.15, -1.36	
Difference (95% CI) in CFB [2]		-3.30 (-5.16, -1.43)		-9.03 (-16.36, -1.69)	
p-value [3]		<0.001		0.020	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.1a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	52	109	10	6	
Mean (StdDev)	15.03 (6.718)	10.15 (6.244)	19.05 (8.333)	6.49 (7.651)	
Median	15.11	8.42	21.77	4.46	
Min, Max	1.2, 30.0	0.1, 30.0	5.9, 29.9	0.0, 20.6	
C7D1 CFB					
n	52	109	10	6	
LS Mean (StdErr) [2]	-2.31 (0.897)	-5.76 (0.652)	-1.21 (2.923)	-10.41 (4.226)	
95% CI [2]	-4.08, -0.54	-7.04, -4.47	-7.58, 5.16	-19.62, -1.20	
Difference (95% CI) in CFB [2]		-3.45 (-5.38, -1.51)		-9.20 (-16.38, -2.02)	
Hedges'G (95% CI) in CFB		-0.51 (-0.86, -0.18)		-0.90 (-2.22, 0.11)	
p-value [3]		<0.001		0.016	
					0.101

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.1a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	56	117	11	6	
Mean (StdDev)	14.36 (6.830)	14.09 (6.513)	7.26 (2.552)	11.18 (5.269)	
Median	13.08	14.00	7.69	12.39	
Min, Max	0.4, 29.1	2.2, 29.6	2.2, 11.3	1.9, 16.3	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.1a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	56	113	11	6	
Mean (StdDev)	12.83 (6.769)	12.22 (6.632)	6.71 (2.866)	8.96 (5.359)	
Median	11.16	11.14	6.79	11.39	
Min, Max	0.2, 27.4	1.1, 30.0	1.2, 11.4	0.0, 13.6	
C2D1 CFB					
n	56	113	11	6	
LS Mean (StdErr) [2]	-1.38 (0.459)	-1.86 (0.346)	-0.16 (1.273)	-2.97 (1.855)	
95% CI [2]	-2.29, -0.48	-2.54, -1.17	-2.91, 2.59	-6.98, 1.04	
Difference (95% CI) in CFB [2]		-0.47 (-1.47, 0.52)		-2.81 (-5.93, 0.31)	
p-value [3]		0.350		0.073	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.1a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	56	111	11	6	
Mean (StdDev)	11.90 (6.555)	11.11 (6.627)	6.04 (3.515)	7.74 (5.777)	
Median	10.48	9.86	4.93	9.25	
Min, Max	0.1, 27.3	0.1, 30.0	0.3, 11.9	0.0, 14.5	
C3D1 CFB					
n	56	111	11	6	
LS Mean (StdErr) [2]	-2.06 (0.568)	-2.76 (0.429)	-1.53 (1.844)	-6.16 (2.689)	
95% CI [2]	-3.18, -0.94	-3.61, -1.91	-5.52, 2.45	-11.96, -0.35	
Difference (95% CI) in CFB [2]		-0.70 (-1.94, 0.53)		-4.62 (-9.14, -0.10)	
p-value [3]		0.263		0.046	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.1a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	54	111	10	6	
Mean (StdDev)	11.82 (6.522)	10.70 (6.736)	6.40 (3.987)	7.19 (5.666)	
Median	10.64	9.50	5.89	8.25	
Min, Max	0.6, 25.6	0.0, 29.9	0.0, 11.6	0.2, 13.6	
C4D1 CFB					
n	54	111	10	6	
LS Mean (StdErr) [2]	-2.21 (0.687)	-3.21 (0.510)	-0.95 (2.153)	-5.72 (3.113)	
95% CI [2]	-3.57, -0.85	-4.21, -2.20	-5.64, 3.74	-12.51, 1.06	
Difference (95% CI) in CFB [2]		-0.99 (-2.47, 0.48)		-4.77 (-10.06, 0.52)	
p-value [3]		0.185		0.073	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.1a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	54	113	9	6	
Mean (StdDev)	11.41 (6.790)	10.47 (6.636)	6.50 (3.848)	4.87 (3.753)	
Median	10.20	8.92	5.29	6.14	
Min, Max	0.5, 26.2	0.0, 30.0	0.1, 12.5	0.0, 9.1	
C5D1 CFB					
n	54	113	9	6	
LS Mean (StdErr) [2]	-2.54 (0.701)	-3.32 (0.512)	-0.92 (1.737)	-8.07 (2.484)	
95% CI [2]	-3.92, -1.15	-4.33, -2.30	-4.74, 2.91	-13.53, -2.60	
Difference (95% CI) in CFB [2]		-0.78 (-2.29, 0.73)		-7.15 (-11.43, -2.87)	
p-value [3]		0.310		0.004	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.1a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	52	112	10	6	
Mean (StdDev)	11.05 (6.400)	9.71 (6.813)	6.45 (3.696)	5.06 (3.984)	
Median	9.38	8.54	6.00	6.75	
Min, Max	0.1, 25.0	0.1, 30.0	0.0, 12.0	0.0, 8.7	
C6D1 CFB					
n	52	112	10	6	
LS Mean (StdErr) [2]	-2.74 (0.737)	-3.98 (0.532)	-0.82 (1.692)	-7.81 (2.447)	
95% CI [2]	-4.19, -1.28	-5.03, -2.93	-4.50, 2.87	-13.14, -2.48	
Difference (95% CI) in CFB [2]		-1.24 (-2.84, 0.35)		-6.99 (-11.15, -2.83)	
p-value [3]		0.125		0.003	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.1a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	52	109	10	6	
Mean (StdDev)	11.01 (6.758)	9.65 (6.802)	7.14 (3.954)	4.75 (3.909)	
Median	10.24	9.00	7.37	5.29	
Min, Max	0.0, 23.4	0.0, 30.0	0.0, 12.9	0.0, 9.0	
C7D1 CFB					
n	52	109	10	6	
LS Mean (StdErr) [2]	-2.85 (0.747)	-3.99 (0.543)	-0.92 (1.892)	-9.32 (2.737)	
95% CI [2]	-4.33, -1.37	-5.06, -2.91	-5.05, 3.20	-15.29, -3.36	
Difference (95% CI) in CFB [2]		-1.14 (-2.75, 0.48)		-8.40 (-13.05, -3.75)	
Hedges'G (95% CI) in CFB		-0.20 (-0.54, 0.13)		-1.27 (-2.71, -0.26)	
p-value [3]		0.166		0.002	
					0.109

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.2a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	15	35	52	88	
Mean (StdDev)	12.43 (7.316)	10.31 (5.462)	10.45 (6.579)	10.48 (6.293)	
Median	12.07	9.69	9.85	9.14	
Min, Max	0.0, 23.8	2.7, 26.8	0.1, 28.0	0.1, 26.3	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.2a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	15	34	52	85	
Mean (StdDev)	10.16 (5.488)	8.57 (5.379)	8.46 (6.563)	8.45 (6.055)	
Median	11.45	7.72	7.32	7.21	
Min, Max	0.0, 20.4	0.2, 21.4	0.5, 26.4	0.0, 24.0	
C2D1 CFB					
n	15	34	52	85	
LS Mean (StdErr) [2]	-2.19 (0.849)	-1.55 (0.579)	-1.71 (0.462)	-1.79 (0.402)	
95% CI [2]	-3.90, -0.48	-2.72, -0.39	-2.62, -0.80	-2.59, -1.00	
Difference (95% CI) in CFB [2]		0.63 (-1.28, 2.55)		-0.08 (-1.09, 0.93)	
p-value [3]		0.509		0.871	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.2a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	34	52	83	
Mean (StdDev)	8.25 (6.094)	8.51 (4.667)	8.15 (6.428)	7.14 (5.913)	
Median	8.15	8.11	6.95	5.21	
Min, Max	0.0, 22.0	0.5, 22.2	0.1, 23.9	0.0, 24.0	
C3D1 CFB					
n	15	34	52	83	
LS Mean (StdErr) [2]	-3.77 (1.052)	-1.34 (0.718)	-2.22 (0.591)	-3.19 (0.515)	
95% CI [2]	-5.88, -1.65	-2.79, 0.10	-3.39, -1.05	-4.21, -2.18	
Difference (95% CI) in CFB [2]		2.42 (0.05, 4.80)		-0.97 (-2.27, 0.32)	
p-value [3]		0.045		0.139	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.2a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	15	34	49	83	
Mean (StdDev)	8.42 (6.552)	7.37 (4.904)	8.43 (6.154)	6.74 (6.005)	
Median	9.15	6.37	7.57	5.50	
Min, Max	0.0, 21.4	0.1, 20.3	0.5, 23.5	0.0, 24.8	
C4D1 CFB					
n	15	34	49	83	
LS Mean (StdErr) [2]	-3.67 (1.230)	-2.55 (0.839)	-2.14 (0.704)	-3.57 (0.597)	
95% CI [2]	-6.15, -1.19	-4.24, -0.86	-3.53, -0.75	-4.75, -2.38	
Difference (95% CI) in CFB [2]		1.12 (-1.65, 3.89)		-1.42 (-2.94, 0.09)	
p-value [3]		0.420		0.065	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.2a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	34	48	85	
Mean (StdDev)	8.65 (5.966)	6.72 (4.126)	8.46 (6.004)	6.69 (6.459)	
Median	8.00	6.34	7.32	4.71	
Min, Max	0.0, 20.2	0.0, 15.5	0.3, 23.3	0.0, 25.0	
C5D1 CFB					
n	15	34	48	85	
LS Mean (StdErr) [2]	-3.27 (1.118)	-3.06 (0.763)	-2.24 (0.812)	-3.61 (0.664)	
95% CI [2]	-5.52, -1.02	-4.60, -1.53	-3.85, -0.64	-4.93, -2.30	
Difference (95% CI) in CFB [2]		0.21 (-2.31, 2.73)		-1.37 (-3.11, 0.37)	
p-value [3]		0.868		0.122	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.2a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	15	34	47	84	
Mean (StdDev)	7.89 (6.153)	6.49 (4.458)	7.31 (5.903)	6.17 (6.119)	
Median	7.93	6.25	5.00	4.31	
Min, Max	0.0, 20.8	0.0, 18.0	0.2, 20.4	0.0, 25.5	
C6D1 CFB					
n	15	34	47	84	
LS Mean (StdErr) [2]	-4.13 (1.310)	-3.41 (0.891)	-2.72 (0.759)	-3.84 (0.623)	
95% CI [2]	-6.77, -1.49	-5.21, -1.62	-4.22, -1.22	-5.07, -2.60	
Difference (95% CI) in CFB [2]		0.72 (-2.24, 3.67)		-1.12 (-2.76, 0.53)	
p-value [3]		0.628		0.182	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.2a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	15	34	47	81	
Mean (StdDev)	8.21 (6.672)	6.55 (4.415)	7.56 (6.203)	6.14 (6.131)	
Median	6.08	5.68	6.36	4.64	
Min, Max	0.0, 22.5	0.0, 17.7	0.1, 22.9	0.0, 26.4	
C7D1 CFB					
n	15	34	47	81	
LS Mean (StdErr) [2]	-3.76 (1.346)	-3.26 (0.918)	-2.64 (0.812)	-3.89 (0.670)	
95% CI [2]	-6.47, -1.05	-5.11, -1.41	-4.24, -1.03	-5.21, -2.56	
Difference (95% CI) in CFB [2]		0.50 (-2.53, 3.54)		-1.25 (-3.01, 0.50)	
Hedges'G (95% CI) in CFB		0.09 (-0.53, 0.72)		-0.21 (-0.58, 0.15)	
p-value [3]		0.740		0.160	
					0.297

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.2a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	15	35	52	88	
Mean (StdDev)	19.44 (5.523)	14.29 (6.800)	17.51 (7.536)	17.22 (6.542)	
Median	19.71	13.86	17.82	17.77	
Min, Max	11.0, 30.0	1.9, 30.0	0.0, 30.0	2.4, 30.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.2a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	15	34	52	85	
Mean (StdDev)	16.85 (5.609)	12.80 (6.145)	16.14 (7.549)	14.05 (5.938)	
Median	16.79	12.26	16.41	14.14	
Min, Max	9.4, 29.2	1.0, 26.8	0.0, 29.8	0.0, 28.5	
C2D1 CFB					
n	15	34	52	85	
LS Mean (StdErr) [2]	-3.07 (0.839)	-1.99 (0.573)	-1.17 (0.570)	-2.97 (0.496)	
95% CI [2]	-4.76, -1.38	-3.14, -0.83	-2.30, -0.05	-3.95, -1.99	
Difference (95% CI) in CFB [2]		1.08 (-0.81, 2.98)		-1.80 (-3.04, -0.55)	
p-value [3]		0.256		0.005	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.2a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	34	52	83	
Mean (StdDev)	16.57 (7.362)	11.16 (5.914)	15.55 (7.394)	12.40 (6.137)	
Median	18.77	9.84	15.01	11.64	
Min, Max	3.7, 28.9	2.3, 24.1	0.0, 29.4	0.1, 28.1	
C3D1 CFB					
n	15	34	52	83	
LS Mean (StdErr) [2]	-2.88 (1.092)	-3.27 (0.745)	-1.40 (0.724)	-4.27 (0.631)	
95% CI [2]	-5.08, -0.68	-4.77, -1.77	-2.83, 0.03	-5.52, -3.03	
Difference (95% CI) in CFB [2]		-0.39 (-2.85, 2.07)		-2.87 (-4.46, -1.29)	
p-value [3]		0.751		<0.001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.2a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	15	34	49	83	
Mean (StdDev)	15.61 (7.209)	10.65 (6.091)	15.56 (7.621)	11.64 (6.241)	
Median	15.07	9.32	16.15	11.21	
Min, Max	4.1, 29.7	1.8, 24.5	0.0, 29.6	0.0, 28.6	
C4D1 CFB					
n	15	34	49	83	
LS Mean (StdErr) [2]	-3.61 (1.295)	-3.60 (0.884)	-1.47 (0.800)	-5.17 (0.679)	
95% CI [2]	-6.22, -1.00	-5.38, -1.82	-3.05, 0.12	-6.51, -3.82	
Difference (95% CI) in CFB [2]		0.02 (-2.91, 2.94)		-3.70 (-5.42, -1.98)	
p-value [3]		0.992		<0.0001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.2a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	34	48	85	
Mean (StdDev)	16.15 (7.169)	10.23 (5.961)	15.45 (7.578)	10.86 (6.171)	
Median	17.14	9.28	15.80	10.21	
Min, Max	5.1, 29.9	1.9, 25.2	0.0, 30.0	0.1, 28.5	
C5D1 CFB					
n	15	34	48	85	
LS Mean (StdErr) [2]	-2.97 (1.373)	-3.94 (0.937)	-1.60 (0.869)	-5.80 (0.711)	
95% CI [2]	-5.73, -0.20	-5.82, -2.05	-3.32, 0.12	-7.20, -4.39	
Difference (95% CI) in CFB [2]		-0.97 (-4.07, 2.12)		-4.20 (-6.06, -2.33)	
p-value [3]		0.531		<0.0001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.2a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	15	34	47	84	
Mean (StdDev)	16.40 (6.830)	9.88 (5.210)	15.16 (7.658)	10.47 (6.734)	
Median	16.57	8.98	15.25	9.70	
Min, Max	5.6, 29.6	1.1, 23.1	0.0, 30.0	0.1, 30.0	
C6D1 CFB					
n	15	34	47	84	
LS Mean (StdErr) [2]	-2.87 (1.370)	-4.45 (0.932)	-1.91 (0.977)	-6.15 (0.802)	
95% CI [2]	-5.63, -0.11	-6.32, -2.57	-3.84, 0.02	-7.73, -4.56	
Difference (95% CI) in CFB [2]		-1.58 (-4.67, 1.51)		-4.23 (-6.35, -2.12)	
p-value [3]		0.309		<0.001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.2a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	15	34	47	81	
Mean (StdDev)	16.57 (7.197)	9.71 (5.211)	15.39 (7.103)	10.07 (6.783)	
Median	16.93	8.35	15.00	8.42	
Min, Max	6.0, 30.0	2.3, 22.8	1.2, 30.0	0.0, 30.0	
C7D1 CFB					
n	15	34	47	81	
LS Mean (StdErr) [2]	-2.63 (1.515)	-4.50 (1.034)	-2.04 (0.991)	-6.55 (0.817)	
95% CI [2]	-5.68, 0.42	-6.59, -2.42	-4.00, -0.07	-8.16, -4.93	
Difference (95% CI) in CFB [2]		-1.88 (-5.29, 1.54)		-4.51 (-6.65, -2.37)	
Hedges'G (95% CI) in CFB		-0.31 (-0.95, 0.30)		-0.63 (-1.01, -0.27)	
p-value [3]		0.275		<0.0001	
					0.206

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.2a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	15	35	52	88	
Mean (StdDev)	14.41 (7.533)	11.69 (6.025)	12.84 (6.674)	14.85 (6.454)	
Median	15.71	10.31	12.43	14.53	
Min, Max	3.0, 23.6	2.2, 26.6	0.4, 29.1	1.9, 29.6	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.2a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	15	34	52	85	
Mean (StdDev)	12.51 (6.907)	10.80 (6.039)	11.62 (6.671)	12.56 (6.771)	
Median	12.29	9.29	9.68	11.79	
Min, Max	1.8, 22.5	1.9, 25.1	0.2, 27.4	0.0, 30.0	
C2D1 CFB					
n	15	34	52	85	
LS Mean (StdErr) [2]	-2.35 (0.625)	-1.37 (0.426)	-1.03 (0.516)	-2.12 (0.449)	
95% CI [2]	-3.61, -1.10	-2.23, -0.51	-2.05, -0.00	-3.01, -1.24	
Difference (95% CI) in CFB [2]		0.99 (-0.42, 2.39)		-1.10 (-2.23, 0.03)	
p-value [3]		0.166		0.056	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.2a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	34	52	83	
Mean (StdDev)	11.18 (6.940)	10.00 (5.145)	10.86 (6.458)	11.33 (7.112)	
Median	10.62	8.86	9.24	10.36	
Min, Max	1.1, 22.9	3.2, 23.3	0.1, 27.3	0.0, 30.0	
C3D1 CFB					
n	15	34	52	83	
LS Mean (StdErr) [2]	-3.61 (0.783)	-2.10 (0.535)	-1.66 (0.648)	-3.26 (0.564)	
95% CI [2]	-5.19, -2.03	-3.17, -1.02	-2.94, -0.38	-4.38, -2.14	
Difference (95% CI) in CFB [2]		1.51 (-0.25, 3.28)		-1.60 (-3.02, -0.18)	
p-value [3]		0.091		0.027	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.2a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	15	34	49	83	
Mean (StdDev)	11.49 (7.293)	9.93 (5.468)	10.81 (6.284)	10.76 (7.172)	
Median	10.21	8.66	9.86	9.50	
Min, Max	1.3, 25.1	1.9, 24.1	0.0, 25.6	0.0, 29.9	
C4D1 CFB					
n	15	34	49	83	
LS Mean (StdErr) [2]	-3.15 (0.904)	-2.04 (0.617)	-1.96 (0.797)	-3.97 (0.676)	
95% CI [2]	-4.97, -1.32	-3.29, -0.80	-3.54, -0.38	-5.31, -2.63	
Difference (95% CI) in CFB [2]		1.10 (-0.94, 3.14)		-2.01 (-3.72, -0.30)	
p-value [3]		0.282		0.022	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.2a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	34	48	85	
Mean (StdDev)	11.03 (7.565)	9.26 (5.623)	10.61 (6.433)	10.56 (6.984)	
Median	10.14	7.86	9.61	9.08	
Min, Max	1.1, 23.2	1.5, 22.8	0.1, 26.2	0.0, 30.0	
C5D1 CFB					
n	15	34	48	85	
LS Mean (StdErr) [2]	-3.23 (0.893)	-2.42 (0.609)	-2.17 (0.828)	-4.00 (0.677)	
95% CI [2]	-5.03, -1.43	-3.65, -1.19	-3.80, -0.53	-5.34, -2.66	
Difference (95% CI) in CFB [2]		0.81 (-1.20, 2.83)		-1.84 (-3.61, -0.06)	
p-value [3]		0.421		0.043	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.2a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	15	34	47	84	
Mean (StdDev)	10.94 (6.885)	8.77 (5.464)	10.11 (6.111)	9.76 (7.236)	
Median	9.54	7.00	8.86	8.54	
Min, Max	2.0, 22.3	1.6, 22.4	0.0, 25.0	0.0, 30.0	
C6D1 CFB					
n	15	34	47	84	
LS Mean (StdErr) [2]	-3.68 (0.981)	-3.05 (0.667)	-2.28 (0.847)	-4.64 (0.695)	
95% CI [2]	-5.65, -1.70	-4.40, -1.71	-3.96, -0.61	-6.01, -3.26	
Difference (95% CI) in CFB [2]		0.63 (-1.59, 2.84)		-2.36 (-4.19, -0.52)	
p-value [3]		0.572		0.012	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.2a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	15	34	47	81	
Mean (StdDev)	10.91 (7.059)	9.00 (5.560)	10.22 (6.414)	9.55 (7.230)	
Median	10.50	8.02	8.58	9.00	
Min, Max	2.4, 23.2	1.7, 22.5	0.0, 23.4	0.0, 30.0	
C7D1 CFB					
n	15	34	47	81	
LS Mean (StdErr) [2]	-3.66 (0.970)	-2.92 (0.662)	-2.27 (0.871)	-4.73 (0.718)	
95% CI [2]	-5.62, -1.71	-4.25, -1.59	-4.00, -0.55	-6.15, -3.30	
Difference (95% CI) in CFB [2]		0.74 (-1.45, 2.93)		-2.46 (-4.34, -0.57)	
Hedges'G (95% CI) in CFB		0.19 (-0.43, 0.82)		-0.39 (-0.76, -0.03)	
p-value [3]		0.498		0.011	
					0.070

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.3a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	32	52	35	71	
Mean (StdDev)	10.23 (7.102)	11.27 (6.617)	11.50 (6.444)	9.81 (5.560)	
Median	9.45	9.63	10.85	9.14	
Min, Max	0.0, 28.0	2.2, 26.8	0.1, 23.8	0.1, 24.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.3a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	32	51	35	68	
Mean (StdDev)	8.36 (6.751)	9.31 (5.825)	9.28 (6.002)	7.87 (5.831)	
Median	6.88	7.77	8.29	6.14	
Min, Max	0.0, 26.4	1.0, 24.0	0.5, 21.9	0.0, 21.4	
C2D1 CFB					
n	32	51	35	68	
LS Mean (StdErr) [2]	-2.03 (0.543)	-2.10 (0.471)	-1.74 (0.572)	-1.50 (0.437)	
95% CI [2]	-3.11, -0.95	-3.04, -1.16	-2.87, -0.60	-2.37, -0.64	
Difference (95% CI) in CFB [2]		-0.07 (-1.29, 1.15)		0.23 (-1.02, 1.48)	
p-value [3]		0.906		0.714	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.3a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	32	50	35	67	
Mean (StdDev)	8.18 (6.783)	8.38 (5.642)	8.16 (5.943)	6.91 (5.518)	
Median	6.61	7.89	8.00	5.62	
Min, Max	0.0, 23.9	0.5, 24.0	0.1, 21.6	0.0, 22.2	
C3D1 CFB					
n	32	50	35	67	
LS Mean (StdErr) [2]	-2.25 (0.810)	-3.09 (0.705)	-2.72 (0.663)	-2.20 (0.507)	
95% CI [2]	-3.86, -0.64	-4.49, -1.68	-4.04, -1.41	-3.21, -1.20	
Difference (95% CI) in CFB [2]		-0.84 (-2.66, 0.99)		0.52 (-0.93, 1.97)	
p-value [3]		0.366		0.476	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.3a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	30	50	34	67	
Mean (StdDev)	8.02 (6.541)	7.64 (5.986)	8.79 (5.952)	6.38 (5.449)	
Median	6.75	6.36	8.75	5.36	
Min, Max	0.0, 23.5	0.0, 24.8	0.0, 19.8	0.0, 24.1	
C4D1 CFB					
n	30	50	34	67	
LS Mean (StdErr) [2]	-2.76 (0.988)	-3.84 (0.827)	-2.37 (0.750)	-2.88 (0.569)	
95% CI [2]	-4.72, -0.79	-5.49, -2.19	-3.86, -0.88	-4.01, -1.75	
Difference (95% CI) in CFB [2]		-1.08 (-3.26, 1.09)		-0.51 (-2.14, 1.12)	
p-value [3]		0.325		0.535	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.3a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	29	51	34	68	
Mean (StdDev)	8.28 (6.713)	7.28 (6.094)	8.69 (5.304)	6.27 (5.704)	
Median	7.50	6.38	7.86	4.78	
Min, Max	0.0, 23.3	0.0, 24.4	0.0, 19.9	0.0, 25.0	
C5D1 CFB					
n	29	51	34	68	
LS Mean (StdErr) [2]	-2.63 (1.035)	-4.12 (0.830)	-2.36 (0.857)	-2.93 (0.645)	
95% CI [2]	-4.69, -0.57	-5.77, -2.46	-4.06, -0.66	-4.21, -1.65	
Difference (95% CI) in CFB [2]		-1.48 (-3.77, 0.80)		-0.57 (-2.43, 1.29)	
p-value [3]		0.199		0.546	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.3a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	28	50	34	68	
Mean (StdDev)	6.79 (6.364)	6.68 (6.019)	7.99 (5.563)	5.94 (5.429)	
Median	4.76	5.64	8.00	4.22	
Min, Max	0.0, 20.8	0.0, 25.5	0.1, 18.9	0.0, 22.7	
C6D1 CFB					
n	28	50	34	68	
LS Mean (StdErr) [2]	-3.53 (1.068)	-4.68 (0.856)	-2.87 (0.787)	-3.10 (0.588)	
95% CI [2]	-5.66, -1.40	-6.39, -2.98	-4.43, -1.31	-4.27, -1.93	
Difference (95% CI) in CFB [2]		-1.16 (-3.54, 1.23)		-0.23 (-1.94, 1.47)	
p-value [3]		0.337		0.786	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.3a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	29	49	33	66	
Mean (StdDev)	7.26 (7.008)	6.32 (5.582)	8.12 (5.622)	6.22 (5.762)	
Median	5.50	5.67	7.31	4.64	
Min, Max	0.0, 22.9	0.0, 24.9	0.2, 19.3	0.0, 26.4	
C7D1 CFB					
n	29	49	33	66	
LS Mean (StdErr) [2]	-3.26 (1.118)	-4.82 (0.922)	-2.76 (0.849)	-2.96 (0.630)	
95% CI [2]	-5.49, -1.03	-6.66, -2.98	-4.44, -1.07	-4.21, -1.71	
Difference (95% CI) in CFB [2]		-1.56 (-4.04, 0.93)		-0.20 (-2.04, 1.64)	
Hedges'G (95% CI) in CFB		-0.24 (-0.72, 0.22)		-0.04 (-0.46, 0.38)	
p-value [3]		0.215		0.831	
					0.346

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.3a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	32	52	35	71	
Mean (StdDev)	19.14 (6.911)	16.64 (7.013)	16.85 (7.273)	16.20 (6.542)	
Median	19.00	15.38	18.36	17.54	
Min, Max	1.1, 30.0	2.4, 30.0	0.0, 30.0	1.9, 29.8	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.3a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	32	51	35	68	
Mean (StdDev)	17.52 (6.971)	14.22 (6.292)	15.18 (7.185)	13.30 (5.784)	
Median	17.43	14.42	16.14	12.89	
Min, Max	3.1, 29.8	0.0, 27.4	0.0, 29.8	1.0, 28.5	
C2D1 CFB					
n	32	51	35	68	
LS Mean (StdErr) [2]	-2.00 (0.581)	-2.82 (0.504)	-1.31 (0.736)	-2.65 (0.562)	
95% CI [2]	-3.16, -0.85	-3.83, -1.82	-2.77, 0.15	-3.77, -1.54	
Difference (95% CI) in CFB [2]		-0.82 (-2.13, 0.49)		-1.34 (-2.95, 0.26)	
p-value [3]		0.215		0.100	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.3a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	32	50	35	67	
Mean (StdDev)	17.20 (7.519)	12.51 (6.517)	14.48 (7.035)	11.68 (5.746)	
Median	16.75	11.57	14.86	10.64	
Min, Max	2.2, 29.4	0.1, 25.4	0.0, 28.9	1.5, 28.1	
C3D1 CFB					
n	32	50	35	67	
LS Mean (StdErr) [2]	-1.94 (0.699)	-4.10 (0.608)	-1.69 (0.955)	-4.02 (0.730)	
95% CI [2]	-3.33, -0.54	-5.31, -2.89	-3.59, 0.20	-5.47, -2.57	
Difference (95% CI) in CFB [2]		-2.17 (-3.74, -0.59)		-2.33 (-4.42, -0.24)	
p-value [3]		0.008		0.029	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.3a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	30	50	34	67	
Mean (StdDev)	16.85 (7.776)	11.78 (6.477)	14.44 (7.113)	11.03 (5.993)	
Median	17.35	11.47	14.79	10.14	
Min, Max	2.8, 29.6	0.0, 24.5	0.0, 29.7	1.7, 28.6	
C4D1 CFB					
n	30	50	34	67	
LS Mean (StdErr) [2]	-2.74 (0.887)	-4.99 (0.742)	-1.42 (1.005)	-4.59 (0.762)	
95% CI [2]	-4.50, -0.97	-6.46, -3.51	-3.42, 0.57	-6.10, -3.07	
Difference (95% CI) in CFB [2]		-2.25 (-4.20, -0.30)		-3.17 (-5.35, -0.98)	
p-value [3]		0.025		0.005	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.3a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	29	51	34	68	
Mean (StdDev)	17.12 (8.028)	10.79 (6.062)	14.34 (6.738)	10.59 (6.161)	
Median	17.14	10.21	14.64	9.79	
Min, Max	1.4, 30.0	0.1, 25.2	0.0, 29.9	0.3, 28.5	
C5D1 CFB					
n	29	51	34	68	
LS Mean (StdErr) [2]	-2.58 (0.922)	-5.94 (0.740)	-1.50 (1.109)	-4.84 (0.835)	
95% CI [2]	-4.42, -0.75	-7.42, -4.47	-3.70, 0.70	-6.50, -3.19	
Difference (95% CI) in CFB [2]		-3.36 (-5.39, -1.33)		-3.35 (-5.75, -0.94)	
p-value [3]		0.002		0.007	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.3a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	28	50	34	68	
Mean (StdDev)	16.81 (7.627)	10.52 (6.086)	14.36 (7.189)	10.14 (6.520)	
Median	17.10	10.34	14.89	8.54	
Min, Max	2.0, 30.0	0.1, 24.9	0.0, 29.6	0.7, 30.0	
C6D1 CFB					
n	28	50	34	68	
LS Mean (StdErr) [2]	-3.07 (1.026)	-6.20 (0.822)	-1.44 (1.193)	-5.31 (0.892)	
95% CI [2]	-5.11, -1.03	-7.84, -4.56	-3.80, 0.93	-7.08, -3.54	
Difference (95% CI) in CFB [2]		-3.13 (-5.42, -0.85)		-3.88 (-6.47, -1.29)	
p-value [3]		0.008		0.004	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.3a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	29	49	33	66	
Mean (StdDev)	16.79 (7.924)	9.79 (6.137)	14.70 (6.214)	10.09 (6.527)	
Median	16.93	8.57	14.64	7.75	
Min, Max	1.2, 30.0	0.1, 24.1	4.2, 30.0	0.0, 30.0	
C7D1 CFB					
n	29	49	33	66	
LS Mean (StdErr) [2]	-3.25 (1.066)	-7.01 (0.879)	-1.23 (1.229)	-5.13 (0.912)	
95% CI [2]	-5.37, -1.13	-8.77, -5.26	-3.67, 1.21	-6.94, -3.32	
Difference (95% CI) in CFB [2]		-3.76 (-6.13, -1.39)		-3.91 (-6.57, -1.24)	
Hedges'G (95% CI) in CFB		-0.62 (-1.12, -0.16)		-0.53 (-0.97, -0.11)	
p-value [3]		0.002		0.004	
					0.974

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.3a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	32	52	35	71	
Mean (StdDev)	13.75 (7.046)	13.70 (5.670)	12.68 (6.722)	14.14 (7.032)	
Median	12.43	13.82	12.50	13.86	
Min, Max	0.4, 29.1	2.2, 26.6	2.2, 24.5	1.9, 29.6	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.3a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	32	51	35	68	
Mean (StdDev)	11.80 (7.038)	12.13 (5.739)	11.85 (6.443)	12.00 (7.210)	
Median	10.32	12.07	10.14	10.14	
Min, Max	0.2, 27.4	1.1, 26.4	1.2, 24.4	0.0, 30.0	
C2D1 CFB					
n	32	51	35	68	
LS Mean (StdErr) [2]	-2.35 (0.539)	-2.04 (0.468)	-0.43 (0.614)	-1.81 (0.469)	
95% CI [2]	-3.43, -1.28	-2.97, -1.11	-1.65, 0.79	-2.74, -0.88	
Difference (95% CI) in CFB [2]		0.31 (-0.90, 1.53)		-1.38 (-2.72, -0.04)	
p-value [3]		0.609		0.044	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.3a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	32	50	35	67	
Mean (StdDev)	11.46 (6.642)	11.00 (5.564)	10.46 (6.458)	10.90 (7.330)	
Median	10.37	10.14	9.07	9.08	
Min, Max	0.1, 27.3	1.1, 26.1	0.3, 22.5	0.0, 30.0	
C3D1 CFB					
n	32	50	35	67	
LS Mean (StdErr) [2]	-2.51 (0.709)	-2.92 (0.617)	-1.67 (0.772)	-2.82 (0.590)	
95% CI [2]	-3.92, -1.10	-4.15, -1.69	-3.21, -0.14	-3.99, -1.65	
Difference (95% CI) in CFB [2]		-0.41 (-2.01, 1.19)		-1.14 (-2.83, 0.55)	
p-value [3]		0.608		0.183	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.3a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	30	50	34	67	
Mean (StdDev)	10.73 (6.553)	10.23 (5.861)	11.19 (6.506)	10.73 (7.315)	
Median	9.07	9.18	10.82	9.50	
Min, Max	0.6, 25.6	0.1, 25.6	0.0, 25.1	0.0, 29.9	
C4D1 CFB					
n	30	50	34	67	
LS Mean (StdErr) [2]	-3.51 (0.917)	-3.82 (0.767)	-1.15 (0.864)	-3.03 (0.655)	
95% CI [2]	-5.33, -1.68	-5.34, -2.29	-2.87, 0.56	-4.33, -1.73	
Difference (95% CI) in CFB [2]		-0.31 (-2.33, 1.71)		-1.88 (-3.75, 0.00)	
p-value [3]		0.762		0.050	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.3a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	29	51	34	68	
Mean (StdDev)	10.74 (7.305)	9.79 (5.746)	10.68 (6.165)	10.49 (7.244)	
Median	10.00	8.22	9.79	9.23	
Min, Max	0.5, 26.2	1.7, 25.8	0.1, 23.2	0.0, 30.0	
C5D1 CFB					
n	29	51	34	68	
LS Mean (StdErr) [2]	-3.56 (0.920)	-4.10 (0.738)	-1.39 (0.902)	-3.03 (0.679)	
95% CI [2]	-5.39, -1.73	-5.58, -2.63	-3.18, 0.40	-4.37, -1.68	
Difference (95% CI) in CFB [2]		-0.54 (-2.57, 1.49)		-1.64 (-3.59, 0.32)	
p-value [3]		0.595		0.100	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.3a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	28	50	34	68	
Mean (StdDev)	10.10 (6.752)	9.15 (5.646)	10.48 (5.920)	9.70 (7.515)	
Median	8.59	8.25	9.00	7.63	
Min, Max	0.1, 23.4	0.6, 26.2	0.0, 25.0	0.0, 30.0	
C6D1 CFB					
n	28	50	34	68	
LS Mean (StdErr) [2]	-3.94 (0.970)	-4.68 (0.778)	-1.58 (0.919)	-3.72 (0.687)	
95% CI [2]	-5.87, -2.00	-6.23, -3.13	-3.40, 0.25	-5.09, -2.36	
Difference (95% CI) in CFB [2]		-0.75 (-2.91, 1.42)		-2.15 (-4.14, -0.15)	
p-value [3]		0.494		0.035	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.3a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	29	49	33	66	
Mean (StdDev)	10.55 (7.074)	8.84 (5.671)	10.24 (6.106)	9.80 (7.483)	
Median	9.29	8.31	9.21	8.75	
Min, Max	0.0, 23.1	0.1, 26.6	0.0, 23.4	0.0, 30.0	
C7D1 CFB					
n	29	49	33	66	
LS Mean (StdErr) [2]	-3.88 (1.004)	-5.00 (0.828)	-1.55 (0.936)	-3.57 (0.694)	
95% CI [2]	-5.89, -1.88	-6.65, -3.35	-3.40, 0.31	-4.95, -2.20	
Difference (95% CI) in CFB [2]		-1.12 (-3.35, 1.11)		-2.03 (-4.06, -0.00)	
Hedges'G (95% CI) in CFB		-0.20 (-0.67, 0.27)		-0.36 (-0.80, 0.06)	
p-value [3]		0.320		0.050	
					0.603

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.4a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.4a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.4a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.4a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.4a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score

	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.4a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.4a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score						
	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.4a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.4a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

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[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.4a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score

	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.4a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.4a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster						
	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

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[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.4a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.4a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.4a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster			
	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.5a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	22	37	45	86	
Mean (StdDev)	5.58 (3.928)	6.71 (3.278)	13.49 (6.314)	12.03 (6.271)	
Median	5.39	6.08	12.14	11.75	
Min, Max	0.0, 13.3	0.1, 14.8	0.1, 28.0	1.0, 26.8	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.5a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	22	35	45	84	
Mean (StdDev)	4.71 (3.349)	4.86 (3.386)	10.86 (6.497)	9.99 (6.007)	
Median	4.94	4.69	8.79	8.89	
Min, Max	0.0, 10.4	0.0, 15.1	0.6, 26.4	0.3, 24.0	
C2D1 CFB					
n	22	35	45	84	
LS Mean (StdErr) [2]	-0.58 (0.579)	-1.46 (0.428)	-2.59 (0.499)	-2.09 (0.402)	
95% CI [2]	-1.74, 0.58	-2.31, -0.60	-3.58, -1.60	-2.89, -1.30	
Difference (95% CI) in CFB [2]		-0.87 (-2.14, 0.39)		0.50 (-0.65, 1.65)	
p-value [3]		0.172		0.391	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.5a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	22	35	45	82	
Mean (StdDev)	4.44 (3.535)	4.98 (3.811)	9.99 (6.588)	8.63 (5.891)	
Median	4.55	4.29	8.57	8.18	
Min, Max	0.0, 10.2	0.0, 15.4	0.5, 23.9	0.0, 24.0	
C3D1 CFB					
n	22	35	45	82	
LS Mean (StdErr) [2]	-1.13 (0.709)	-1.51 (0.523)	-3.61 (0.658)	-3.60 (0.533)	
95% CI [2]	-2.55, 0.29	-2.56, -0.46	-4.91, -2.30	-4.65, -2.54	
Difference (95% CI) in CFB [2]		-0.38 (-1.93, 1.17)		0.01 (-1.51, 1.53)	
p-value [3]		0.627		0.992	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

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[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.5a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	20	34	44	83	
Mean (StdDev)	4.75 (3.949)	3.96 (3.005)	10.10 (6.342)	8.13 (6.093)	
Median	4.75	3.40	9.54	6.57	
Min, Max	0.0, 12.4	0.0, 9.4	0.5, 23.5	0.0, 24.8	
C4D1 CFB					
n	20	34	44	83	
LS Mean (StdErr) [2]	-0.54 (0.777)	-2.15 (0.561)	-3.75 (0.767)	-4.27 (0.609)	
95% CI [2]	-2.10, 1.02	-3.27, -1.02	-5.27, -2.23	-5.48, -3.07	
Difference (95% CI) in CFB [2]		-1.61 (-3.32, 0.10)		-0.53 (-2.27, 1.22)	
p-value [3]		0.064		0.552	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.5a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	36	44	83	
Mean (StdDev)	4.92 (3.670)	4.31 (3.705)	10.05 (6.101)	7.74 (6.336)	
Median	6.09	3.61	8.70	6.62	
Min, Max	0.0, 10.4	0.0, 14.1	0.8, 23.3	0.0, 25.0	
C5D1 CFB					
n	19	36	44	83	
LS Mean (StdErr) [2]	-0.34 (0.873)	-1.90 (0.602)	-3.93 (0.829)	-4.82 (0.659)	
95% CI [2]	-2.09, 1.41	-3.11, -0.69	-5.57, -2.29	-6.12, -3.52	
Difference (95% CI) in CFB [2]		-1.56 (-3.47, 0.36)		-0.89 (-2.78, 1.00)	
p-value [3]		0.109		0.353	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.5a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	20	37	42	81	
Mean (StdDev)	4.61 (3.939)	4.18 (3.662)	8.80 (6.255)	7.21 (6.174)	
Median	3.75	4.00	7.18	6.21	
Min, Max	0.0, 12.1	0.0, 16.2	0.2, 20.8	0.0, 25.5	
C6D1 CFB					
n	20	37	42	81	
LS Mean (StdErr) [2]	-0.41 (0.783)	-2.38 (0.546)	-4.96 (0.847)	-5.12 (0.667)	
95% CI [2]	-1.98, 1.16	-3.48, -1.29	-6.64, -3.28	-6.44, -3.80	
Difference (95% CI) in CFB [2]		-1.97 (-3.68, -0.26)		-0.16 (-2.10, 1.77)	
p-value [3]		0.025		0.868	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.5a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	19	36	43	79	
Mean (StdDev)	3.93 (3.651)	4.17 (3.375)	9.39 (6.481)	7.22 (6.228)	
Median	2.92	3.62	8.14	5.67	
Min, Max	0.0, 11.1	0.0, 12.0	0.1, 22.9	0.0, 26.4	
C7D1 CFB					
n	19	36	43	79	
LS Mean (StdErr) [2]	-0.67 (0.737)	-2.12 (0.508)	-4.54 (0.898)	-5.18 (0.725)	
95% CI [2]	-2.15, 0.81	-3.14, -1.10	-6.32, -2.76	-6.62, -3.75	
Difference (95% CI) in CFB [2]		-1.44 (-3.06, 0.18)		-0.64 (-2.70, 1.42)	
Hedges'G (95% CI) in CFB		-0.46 (-1.05, 0.10)		-0.10 (-0.48, 0.27)	
p-value [3]		0.080		0.540	
					0.714

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.5a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	22	37	45	86	
Mean (StdDev)	13.36 (7.262)	11.19 (5.500)	20.18 (5.974)	18.62 (5.932)	
Median	12.23	10.00	20.71	18.39	
Min, Max	0.0, 27.0	1.9, 22.8	2.2, 30.0	3.9, 30.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.5a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	22	35	45	84	
Mean (StdDev)	11.91 (6.941)	9.38 (5.374)	18.44 (6.236)	15.49 (5.311)	
Median	10.25	8.71	17.14	15.46	
Min, Max	0.0, 26.5	0.0, 21.8	2.3, 29.8	2.2, 28.5	
C2D1 CFB					
n	22	35	45	84	
LS Mean (StdErr) [2]	-2.07 (0.607)	-2.13 (0.448)	-1.81 (0.613)	-3.29 (0.494)	
95% CI [2]	-3.29, -0.86	-3.03, -1.23	-3.02, -0.60	-4.26, -2.31	
Difference (95% CI) in CFB [2]		-0.06 (-1.38, 1.27)		-1.47 (-2.89, -0.06)	
p-value [3]		0.934		0.041	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.5a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	22	35	45	82	
Mean (StdDev)	11.69 (7.135)	8.65 (5.166)	17.77 (6.646)	13.48 (5.880)	
Median	9.54	8.07	16.79	12.71	
Min, Max	0.0, 27.5	0.1, 20.7	2.0, 29.4	1.5, 28.1	
C3D1 CFB					
n	22	35	45	82	
LS Mean (StdErr) [2]	-2.36 (0.942)	-2.90 (0.695)	-2.27 (0.738)	-5.16 (0.597)	
95% CI [2]	-4.25, -0.47	-4.29, -1.51	-3.73, -0.80	-6.34, -3.98	
Difference (95% CI) in CFB [2]		-0.54 (-2.60, 1.52)		-2.89 (-4.60, -1.19)	
p-value [3]		0.600		0.001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.5a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	20	34	44	83	
Mean (StdDev)	10.86 (7.158)	7.93 (4.604)	17.71 (6.639)	12.75 (6.230)	
Median	8.21	6.89	18.03	12.54	
Min, Max	0.0, 25.5	0.0, 20.3	2.8, 29.7	1.7, 28.6	
C4D1 CFB					
n	20	34	44	83	
LS Mean (StdErr) [2]	-2.45 (0.873)	-3.50 (0.630)	-2.38 (0.859)	-5.79 (0.683)	
95% CI [2]	-4.20, -0.69	-4.76, -2.23	-4.08, -0.68	-7.14, -4.44	
Difference (95% CI) in CFB [2]		-1.05 (-2.97, 0.87)		-3.42 (-5.37, -1.46)	
p-value [3]		0.276		<0.001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.5a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	36	44	83	
Mean (StdDev)	11.59 (7.323)	7.53 (4.315)	17.36 (6.849)	12.04 (6.265)	
Median	9.83	6.54	17.14	11.23	
Min, Max	0.0, 23.6	0.1, 19.0	2.5, 30.0	0.3, 28.5	
C5D1 CFB					
n	19	36	44	83	
LS Mean (StdErr) [2]	-1.82 (0.974)	-3.93 (0.672)	-2.83 (0.928)	-6.62 (0.737)	
95% CI [2]	-3.78, 0.13	-5.28, -2.59	-4.67, -1.00	-8.08, -5.16	
Difference (95% CI) in CFB [2]		-2.11 (-4.25, 0.03)		-3.79 (-5.90, -1.67)	
p-value [3]		0.053		<0.001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.5a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	20	37	42	81	
Mean (StdDev)	11.74 (6.695)	7.11 (4.155)	17.24 (7.170)	11.76 (6.610)	
Median	11.57	6.14	17.41	11.00	
Min, Max	0.0, 22.9	0.1, 17.9	2.0, 30.0	0.7, 30.0	
C6D1 CFB					
n	20	37	42	81	
LS Mean (StdErr) [2]	-2.31 (1.053)	-4.29 (0.734)	-2.81 (1.028)	-6.98 (0.809)	
95% CI [2]	-4.42, -0.20	-5.76, -2.81	-4.84, -0.77	-8.58, -5.38	
Difference (95% CI) in CFB [2]		-1.98 (-4.28, 0.32)		-4.17 (-6.52, -1.82)	
p-value [3]		0.091		<0.001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.5a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	19	36	43	79	
Mean (StdDev)	12.35 (5.752)	7.15 (4.359)	17.15 (7.177)	11.24 (6.699)	
Median	11.21	6.93	17.00	10.85	
Min, Max	4.2, 23.0	0.1, 19.1	1.2, 30.0	0.0, 30.0	
C7D1 CFB					
n	19	36	43	79	
LS Mean (StdErr) [2]	-2.36 (1.149)	-4.24 (0.793)	-2.95 (1.035)	-7.46 (0.835)	
95% CI [2]	-4.67, -0.05	-5.83, -2.65	-5.00, -0.90	-9.12, -5.81	
Difference (95% CI) in CFB [2]		-1.88 (-4.40, 0.65)		-4.51 (-6.88, -2.14)	
Hedges'G (95% CI) in CFB		-0.38 (-0.97, 0.18)		-0.62 (-1.02, -0.25)	
p-value [3]		0.141		<0.001	
					0.209

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.5a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	22	37	45	86	
Mean (StdDev)	8.12 (4.155)	8.46 (3.419)	15.67 (6.552)	16.31 (6.030)	
Median	8.25	7.91	13.85	15.30	
Min, Max	0.4, 20.0	2.4, 15.4	5.2, 29.1	1.9, 29.6	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.5a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	22	35	45	84	
Mean (StdDev)	7.10 (4.300)	7.36 (3.775)	14.13 (6.444)	14.01 (6.541)	
Median	7.16	6.79	12.29	12.74	
Min, Max	0.2, 19.8	1.1, 16.8	3.4, 27.4	0.0, 30.0	
C2D1 CFB					
n	22	35	45	84	
LS Mean (StdErr) [2]	-1.10 (0.545)	-1.21 (0.402)	-1.67 (0.537)	-2.48 (0.432)	
95% CI [2]	-2.20, -0.01	-2.02, -0.40	-2.73, -0.61	-3.33, -1.62	
Difference (95% CI) in CFB [2]		-0.10 (-1.29, 1.09)		-0.81 (-2.04, 0.43)	
p-value [3]		0.861		0.198	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.5a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	22	35	45	82	
Mean (StdDev)	6.77 (4.573)	6.57 (3.436)	12.97 (6.388)	12.80 (6.767)	
Median	6.05	5.93	11.64	12.02	
Min, Max	0.1, 19.8	1.1, 16.1	1.4, 27.3	0.0, 30.0	
C3D1 CFB					
n	22	35	45	82	
LS Mean (StdErr) [2]	-1.64 (0.749)	-2.12 (0.553)	-2.71 (0.667)	-3.61 (0.540)	
95% CI [2]	-3.14, -0.14	-3.23, -1.01	-4.03, -1.39	-4.68, -2.54	
Difference (95% CI) in CFB [2]		-0.48 (-2.11, 1.16)		-0.90 (-2.44, 0.64)	
p-value [3]		0.561		0.250	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.5a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	20	34	44	83	
Mean (StdDev)	7.37 (4.784)	6.30 (3.878)	12.61 (6.530)	12.24 (6.873)	
Median	6.98	5.64	10.82	11.29	
Min, Max	0.0, 19.2	0.1, 17.7	1.3, 25.6	0.0, 29.9	
C4D1 CFB					
n	20	34	44	83	
LS Mean (StdErr) [2]	-0.52 (0.830)	-2.01 (0.599)	-3.37 (0.804)	-4.47 (0.638)	
95% CI [2]	-2.18, 1.15	-3.21, -0.80	-4.96, -1.78	-5.74, -3.21	
Difference (95% CI) in CFB [2]		-1.49 (-3.31, 0.33)		-1.10 (-2.93, 0.73)	
p-value [3]		0.107		0.235	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.5a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	36	44	83	
Mean (StdDev)	6.22 (4.617)	6.57 (4.086)	12.65 (6.498)	11.76 (6.915)	
Median	5.36	6.17	11.10	10.79	
Min, Max	0.1, 17.4	0.5, 16.3	1.5, 26.2	0.0, 30.0	
C5D1 CFB					
n	19	36	44	83	
LS Mean (StdErr) [2]	-1.58 (0.906)	-1.80 (0.625)	-3.24 (0.810)	-4.86 (0.643)	
95% CI [2]	-3.39, 0.24	-3.05, -0.55	-4.85, -1.64	-6.13, -3.59	
Difference (95% CI) in CFB [2]		-0.22 (-2.21, 1.77)		-1.62 (-3.46, 0.23)	
p-value [3]		0.824		0.085	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.5a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	20	37	42	81	
Mean (StdDev)	7.07 (4.486)	5.97 (3.908)	11.85 (6.435)	11.07 (7.198)	
Median	6.17	5.29	10.39	10.64	
Min, Max	0.0, 17.0	0.1, 15.7	1.3, 25.0	0.0, 30.0	
C6D1 CFB					
n	20	37	42	81	
LS Mean (StdErr) [2]	-0.88 (0.840)	-2.47 (0.585)	-4.01 (0.876)	-5.62 (0.690)	
95% CI [2]	-2.56, 0.81	-3.65, -1.30	-5.74, -2.27	-6.98, -4.25	
Difference (95% CI) in CFB [2]		-1.60 (-3.43, 0.24)		-1.61 (-3.61, 0.39)	
p-value [3]		0.087		0.114	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.5a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	19	36	43	79	
Mean (StdDev)	6.76 (4.362)	6.00 (3.981)	11.99 (6.712)	10.93 (7.209)	
Median	7.21	5.61	11.33	10.33	
Min, Max	0.0, 16.6	0.1, 14.0	1.2, 23.4	0.0, 30.0	
C7D1 CFB					
n	19	36	43	79	
LS Mean (StdErr) [2]	-1.05 (0.907)	-2.54 (0.626)	-3.97 (0.876)	-5.64 (0.708)	
95% CI [2]	-2.87, 0.77	-3.80, -1.29	-5.70, -2.23	-7.04, -4.24	
Difference (95% CI) in CFB [2]		-1.49 (-3.48, 0.50)		-1.67 (-3.68, 0.34)	
Hedges'G (95% CI) in CFB		-0.38 (-0.97, 0.17)		-0.27 (-0.65, 0.10)	
p-value [3]		0.140		0.102	
					0.880

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.6a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score					
	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	13	26	54	97	
Mean (StdDev)	13.62 (6.504)	10.43 (7.063)	10.24 (6.695)	10.43 (5.785)	
Median	14.31	8.46	9.85	10.00	
Min, Max	3.9, 24.9	1.1, 26.3	0.0, 28.0	0.1, 26.8	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.6a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	54	94	
Mean (StdDev)	9.16 (6.512)	10.07 (6.931)	8.76 (6.356)	8.06 (5.489)	
Median	7.21	7.75	7.89	7.29	
Min, Max	1.2, 22.1	1.1, 21.4	0.0, 26.4	0.0, 24.0	
C2D1 CFB					
n	13	25	54	94	
LS Mean (StdErr) [2]	-4.32 (0.955)	-0.43 (0.647)	-1.37 (0.371)	-2.21 (0.297)	
95% CI [2]	-6.26, -2.38	-1.74, 0.88	-2.10, -0.64	-2.79, -1.62	
Difference (95% CI) in CFB [2]		3.89 (1.66, 6.12)		-0.84 (-1.75, 0.07)	
p-value [3]		0.001		0.071	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.6a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	25	54	92	
Mean (StdDev)	7.74 (6.321)	8.88 (6.294)	8.27 (6.361)	7.17 (5.369)	
Median	5.77	8.00	7.67	6.50	
Min, Max	1.7, 21.6	0.1, 22.2	0.0, 23.9	0.0, 24.0	
C3D1 CFB					
n	13	25	54	92	
LS Mean (StdErr) [2]	-5.36 (0.956)	-1.47 (0.647)	-1.72 (0.521)	-2.79 (0.420)	
95% CI [2]	-7.30, -3.42	-2.78, -0.16	-2.75, -0.69	-3.62, -1.96	
Difference (95% CI) in CFB [2]		3.89 (1.66, 6.11)		-1.08 (-2.36, 0.21)	
p-value [3]		0.001		0.100	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.6a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	12	25	52	92	
Mean (StdDev)	8.09 (5.928)	8.25 (6.115)	8.51 (6.310)	6.56 (5.553)	
Median	6.79	6.64	7.72	5.25	
Min, Max	1.2, 19.3	0.0, 24.1	0.0, 23.5	0.0, 24.8	
C4D1 CFB					
n	12	25	52	92	
LS Mean (StdErr) [2]	-5.25 (1.217)	-1.96 (0.801)	-1.72 (0.602)	-3.54 (0.477)	
95% CI [2]	-7.72, -2.78	-3.59, -0.33	-2.91, -0.53	-4.49, -2.60	
Difference (95% CI) in CFB [2]		3.29 (0.46, 6.11)		-1.82 (-3.29, -0.36)	
p-value [3]		0.024		0.015	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.6a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	26	51	93	
Mean (StdDev)	7.53 (5.235)	7.93 (5.469)	8.73 (6.127)	6.36 (5.961)	
Median	6.00	6.96	7.54	4.79	
Min, Max	1.7, 17.3	0.0, 21.1	0.0, 23.3	0.0, 25.0	
C5D1 CFB					
n	12	26	51	93	
LS Mean (StdErr) [2]	-5.50 (1.388)	-2.11 (0.890)	-1.55 (0.653)	-3.71 (0.507)	
95% CI [2]	-8.31, -2.68	-3.92, -0.30	-2.84, -0.26	-4.71, -2.70	
Difference (95% CI) in CFB [2]		3.39 (0.16, 6.61)		-2.15 (-3.72, -0.58)	
p-value [3]		0.040		0.008	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.6a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	26	50	92	
Mean (StdDev)	7.21 (5.663)	7.32 (5.944)	7.51 (6.033)	5.96 (5.591)	
Median	6.14	6.29	5.96	4.75	
Min, Max	0.5, 16.4	0.0, 22.7	0.0, 20.8	0.0, 25.5	
C6D1 CFB					
n	12	26	50	92	
LS Mean (StdErr) [2]	-5.91 (1.466)	-2.75 (0.941)	-2.21 (0.641)	-3.88 (0.494)	
95% CI [2]	-8.89, -2.93	-4.66, -0.84	-3.48, -0.94	-4.86, -2.90	
Difference (95% CI) in CFB [2]		3.16 (-0.24, 6.57)		-1.67 (-3.22, -0.11)	
p-value [3]		0.068		0.036	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.6a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	12	25	50	90	
Mean (StdDev)	7.57 (5.351)	7.25 (5.920)	7.75 (6.519)	5.99 (5.591)	
Median	6.04	5.75	6.49	4.64	
Min, Max	0.5, 16.1	0.0, 26.4	0.0, 22.9	0.0, 24.9	
C7D1 CFB					
n	12	25	50	90	
LS Mean (StdErr) [2]	-5.50 (1.573)	-2.52 (1.022)	-2.15 (0.673)	-3.96 (0.523)	
95% CI [2]	-8.69, -2.30	-4.59, -0.44	-3.49, -0.82	-4.99, -2.92	
Difference (95% CI) in CFB [2]		2.98 (-0.71, 6.67)		-1.80 (-3.43, -0.18)	
Hedges'G (95% CI) in CFB		0.56 (-0.13, 1.32)		-0.37 (-0.72, -0.02)	
p-value [3]		0.110		0.030	
					0.009

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.6a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	13	26	54	97	
Mean (StdDev)	17.72 (5.466)	16.67 (6.716)	18.00 (7.533)	16.31 (6.754)	
Median	17.79	16.85	18.57	16.43	
Min, Max	10.4, 24.4	1.9, 29.8	0.0, 30.0	2.4, 30.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.6a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	54	94	
Mean (StdDev)	14.96 (5.899)	13.90 (6.107)	16.62 (7.405)	13.64 (6.001)	
Median	14.07	14.14	16.54	13.18	
Min, Max	5.6, 23.0	1.0, 23.4	0.0, 29.8	0.0, 28.5	
C2D1 CFB					
n	13	25	54	94	
LS Mean (StdErr) [2]	-2.78 (1.247)	-2.88 (0.844)	-1.22 (0.459)	-2.48 (0.367)	
95% CI [2]	-5.31, -0.25	-4.60, -1.17	-2.13, -0.32	-3.21, -1.76	
Difference (95% CI) in CFB [2]		-0.10 (-3.01, 2.80)		-1.26 (-2.39, -0.14)	
p-value [3]		0.943		0.028	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.6a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	25	54	92	
Mean (StdDev)	14.37 (5.867)	12.92 (6.078)	16.11 (7.665)	11.80 (6.084)	
Median	15.15	13.38	16.25	10.96	
Min, Max	4.9, 23.2	2.3, 23.3	0.0, 29.4	0.1, 28.1	
C3D1 CFB					
n	13	25	54	92	
LS Mean (StdErr) [2]	-3.29 (1.402)	-3.83 (0.949)	-1.57 (0.598)	-4.13 (0.482)	
95% CI [2]	-6.13, -0.44	-5.76, -1.91	-2.75, -0.39	-5.08, -3.18	
Difference (95% CI) in CFB [2]		-0.55 (-3.82, 2.72)		-2.56 (-4.03, -1.08)	
p-value [3]		0.736		<0.001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.6a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	12	25	52	92	
Mean (StdDev)	14.21 (5.692)	12.64 (5.888)	15.88 (7.836)	11.00 (6.252)	
Median	15.32	13.50	16.15	9.96	
Min, Max	2.8, 22.1	2.5, 22.9	0.0, 29.7	0.0, 28.6	
C4D1 CFB					
n	12	25	52	92	
LS Mean (StdErr) [2]	-3.36 (1.561)	-4.02 (1.028)	-1.91 (0.674)	-5.11 (0.535)	
95% CI [2]	-6.54, -0.19	-6.11, -1.94	-3.25, -0.58	-6.17, -4.06	
Difference (95% CI) in CFB [2]		-0.66 (-4.29, 2.96)		-3.20 (-4.84, -1.56)	
p-value [3]		0.713		<0.001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.6a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	26	51	93	
Mean (StdDev)	13.36 (5.391)	11.81 (5.808)	16.15 (7.784)	10.36 (6.164)	
Median	15.14	11.89	16.07	9.23	
Min, Max	2.5, 18.6	1.9, 23.4	0.0, 30.0	0.1, 28.5	
C5D1 CFB					
n	12	26	51	93	
LS Mean (StdErr) [2]	-4.12 (1.693)	-4.75 (1.086)	-1.53 (0.733)	-5.46 (0.569)	
95% CI [2]	-7.55, -0.68	-6.95, -2.54	-2.98, -0.08	-6.58, -4.33	
Difference (95% CI) in CFB [2]		-0.63 (-4.57, 3.31)		-3.93 (-5.69, -2.16)	
p-value [3]		0.747		<0.0001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.6a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	26	50	92	
Mean (StdDev)	13.22 (5.452)	11.59 (6.382)	16.00 (7.781)	9.94 (6.284)	
Median	14.44	11.27	15.83	8.83	
Min, Max	2.0, 18.2	1.1, 29.4	0.0, 30.0	0.1, 30.0	
C6D1 CFB					
n	12	26	50	92	
LS Mean (StdErr) [2]	-4.29 (1.873)	-4.98 (1.202)	-1.78 (0.795)	-5.95 (0.613)	
95% CI [2]	-8.10, -0.49	-7.42, -2.54	-3.35, -0.20	-7.16, -4.74	
Difference (95% CI) in CFB [2]		-0.68 (-5.04, 3.67)		-4.17 (-6.10, -2.24)	
p-value [3]		0.751		<0.0001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.6a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	12	25	50	90	
Mean (StdDev)	13.40 (5.414)	11.37 (6.523)	16.22 (7.371)	9.57 (6.267)	
Median	14.82	10.85	15.80	7.96	
Min, Max	1.2, 20.8	2.3, 28.9	3.1, 30.0	0.0, 30.0	
C7D1 CFB					
n	12	25	50	90	
LS Mean (StdErr) [2]	-3.97 (1.907)	-5.18 (1.239)	-1.93 (0.824)	-6.25 (0.641)	
95% CI [2]	-7.84, -0.09	-7.70, -2.67	-3.56, -0.30	-7.52, -4.98	
Difference (95% CI) in CFB [2]		-1.22 (-5.69, 3.26)		-4.32 (-6.31, -2.33)	
Hedges'G (95% CI) in CFB		-0.19 (-0.92, 0.51)		-0.72 (-1.09, -0.37)	
p-value [3]		0.583		<0.0001	
					0.215

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.6a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	13	26	54	97	
Mean (StdDev)	15.73 (7.016)	14.54 (7.303)	12.58 (6.729)	13.79 (6.261)	
Median	15.71	13.15	11.14	14.00	
Min, Max	5.2, 26.7	2.4, 28.6	0.4, 29.1	1.9, 29.6	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.6a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	54	94	
Mean (StdDev)	12.95 (6.564)	13.10 (7.194)	11.55 (6.742)	11.78 (6.437)	
Median	11.79	12.07	10.00	10.81	
Min, Max	6.2, 24.9	2.8, 28.1	0.2, 27.4	0.0, 30.0	
C2D1 CFB					
n	13	25	54	94	
LS Mean (StdErr) [2]	-2.46 (1.126)	-1.59 (0.763)	-0.93 (0.395)	-1.87 (0.316)	
95% CI [2]	-4.75, -0.18	-3.14, -0.04	-1.71, -0.15	-2.50, -1.25	
Difference (95% CI) in CFB [2]		0.87 (-1.75, 3.50)		-0.94 (-1.91, 0.03)	
p-value [3]		0.503		0.056	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.6a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	25	54	92	
Mean (StdDev)	11.77 (7.111)	12.31 (7.446)	10.73 (6.420)	10.57 (6.353)	
Median	10.50	9.54	9.24	9.71	
Min, Max	4.6, 23.6	2.1, 27.1	0.1, 27.3	0.0, 30.0	
C3D1 CFB					
n	13	25	54	92	
LS Mean (StdErr) [2]	-3.76 (1.386)	-2.42 (0.938)	-1.64 (0.501)	-2.92 (0.404)	
95% CI [2]	-6.58, -0.95	-4.33, -0.52	-2.63, -0.65	-3.72, -2.12	
Difference (95% CI) in CFB [2]		1.34 (-1.89, 4.57)		-1.28 (-2.51, -0.05)	
p-value [3]		0.405		0.042	

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Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.6a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	12	25	52	92	
Mean (StdDev)	11.04 (6.668)	11.49 (6.896)	10.96 (6.503)	10.25 (6.671)	
Median	8.18	10.14	10.29	8.86	
Min, Max	4.9, 23.0	0.0, 26.6	0.0, 25.6	0.1, 29.9	
C4D1 CFB					
n	12	25	52	92	
LS Mean (StdErr) [2]	-3.65 (1.672)	-2.92 (1.101)	-1.47 (0.601)	-3.14 (0.477)	
95% CI [2]	-7.05, -0.26	-5.15, -0.68	-2.65, -0.28	-4.09, -2.20	
Difference (95% CI) in CFB [2]		0.74 (-3.15, 4.62)		-1.68 (-3.14, -0.22)	
p-value [3]		0.702		0.025	

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Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.6a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	26	51	93	
Mean (StdDev)	10.60 (6.102)	11.51 (6.571)	10.74 (6.839)	9.82 (6.630)	
Median	9.50	10.12	9.93	8.08	
Min, Max	3.1, 22.4	0.0, 23.6	0.1, 26.2	0.0, 30.0	
C5D1 CFB					
n	12	26	51	93	
LS Mean (StdErr) [2]	-4.10 (1.730)	-2.69 (1.110)	-1.77 (0.612)	-3.60 (0.475)	
95% CI [2]	-7.61, -0.59	-4.95, -0.44	-2.98, -0.56	-4.54, -2.66	
Difference (95% CI) in CFB [2]		1.40 (-2.62, 5.43)		-1.83 (-3.30, -0.36)	
p-value [3]		0.483		0.015	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.6a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	26	50	92	
Mean (StdDev)	9.43 (6.207)	10.81 (7.280)	10.52 (6.315)	9.09 (6.604)	
Median	7.11	9.41	9.11	7.68	
Min, Max	2.1, 22.5	0.1, 29.6	0.0, 25.0	0.0, 30.0	
C6D1 CFB					
n	12	26	50	92	
LS Mean (StdErr) [2]	-5.23 (1.883)	-3.38 (1.208)	-1.62 (0.618)	-4.07 (0.476)	
95% CI [2]	-9.05, -1.41	-5.83, -0.93	-2.84, -0.40	-5.01, -3.13	
Difference (95% CI) in CFB [2]		1.85 (-2.53, 6.23)		-2.44 (-3.94, -0.95)	
p-value [3]		0.397		0.002	

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Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.6a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	12	25	50	90	
Mean (StdDev)	9.96 (6.468)	10.39 (7.245)	10.49 (6.597)	9.11 (6.635)	
Median	8.99	9.00	9.25	8.39	
Min, Max	1.2, 22.6	0.0, 29.0	0.0, 23.4	0.0, 30.0	
C7D1 CFB					
n	12	25	50	90	
LS Mean (StdErr) [2]	-4.80 (1.925)	-3.56 (1.251)	-1.78 (0.635)	-4.08 (0.494)	
95% CI [2]	-8.71, -0.89	-6.10, -1.01	-3.04, -0.52	-5.06, -3.11	
Difference (95% CI) in CFB [2]		1.24 (-3.28, 5.76)		-2.30 (-3.84, -0.77)	
Hedges'G (95% CI) in CFB		0.19 (-0.51, 0.92)		-0.50 (-0.86, -0.15)	
p-value [3]		0.580		0.004	
					0.063

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.7a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	63	114	4	9	
Mean (StdDev)	10.86 (6.696)	10.33 (5.990)	11.46 (8.581)	11.61 (6.996)	
Median	10.07	9.21	8.36	11.57	
Min, Max	0.0, 28.0	0.1, 26.8	5.4, 23.8	1.0, 26.3	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.7a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	63	110	4	9	
Mean (StdDev)	8.79 (6.486)	8.35 (5.804)	9.70 (3.653)	10.15 (6.479)	
Median	7.43	7.21	9.29	9.29	
Min, Max	0.0, 26.4	0.0, 24.0	5.8, 14.4	1.6, 23.0	
C2D1 CFB					
n	63	110	4	9	
LS Mean (StdErr) [2]	-1.85 (0.407)	-1.79 (0.329)	-0.46 (2.574)	0.14 (2.040)	
95% CI [2]	-2.65, -1.04	-2.44, -1.14	-6.28, 5.36	-4.47, 4.76	
Difference (95% CI) in CFB [2]		0.05 (-0.85, 0.96)		0.60 (-4.42, 5.63)	
p-value [3]		0.907		0.792	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.7a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	63	108	4	9	
Mean (StdDev)	8.02 (6.441)	7.39 (5.477)	10.52 (3.231)	9.29 (6.993)	
Median	6.91	6.52	9.29	8.62	
Min, Max	0.0, 23.9	0.0, 24.0	8.3, 15.2	0.1, 22.8	
C3D1 CFB					
n	63	108	4	9	
LS Mean (StdErr) [2]	-2.54 (0.528)	-2.60 (0.427)	0.49 (3.162)	-1.01 (2.506)	
95% CI [2]	-3.58, -1.50	-3.45, -1.76	-6.67, 7.64	-6.68, 4.65	
Difference (95% CI) in CFB [2]		-0.06 (-1.24, 1.11)		-1.50 (-7.67, 4.67)	
p-value [3]		0.915		0.595	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.7a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	60	108	4	9	
Mean (StdDev)	8.34 (6.359)	6.86 (5.617)	9.73 (2.956)	7.69 (6.886)	
Median	7.25	5.71	10.54	7.64	
Min, Max	0.0, 23.5	0.0, 24.8	5.5, 12.4	0.0, 23.3	
C4D1 CFB					
n	60	108	4	9	
LS Mean (StdErr) [2]	-2.54 (0.617)	-3.25 (0.488)	0.34 (3.832)	-1.51 (3.036)	
95% CI [2]	-3.76, -1.32	-4.22, -2.29	-8.33, 9.01	-8.38, 5.36	
Difference (95% CI) in CFB [2]		-0.72 (-2.07, 0.64)		-1.85 (-9.32, 5.63)	
p-value [3]		0.299		0.590	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.7a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	59	110	4	9	
Mean (StdDev)	8.51 (6.137)	6.39 (5.402)	8.46 (1.654)	10.54 (9.633)	
Median	7.50	5.71	7.88	7.43	
Min, Max	0.0, 23.3	0.0, 23.8	7.2, 10.9	0.0, 25.0	
C5D1 CFB					
n	59	110	4	9	
LS Mean (StdErr) [2]	-2.40 (0.639)	-3.67 (0.493)	1.49 (5.435)	2.73 (4.307)	
95% CI [2]	-3.67, -1.14	-4.64, -2.69	-10.81, 13.78	-7.01, 12.47	
Difference (95% CI) in CFB [2]		-1.26 (-2.66, 0.14)		1.25 (-9.36, 11.85)	
p-value [3]		0.077		0.796	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.7a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	58	109	4	9	
Mean (StdDev)	7.33 (6.071)	6.08 (5.483)	9.29 (2.700)	8.44 (7.683)	
Median	5.11	4.79	9.61	7.00	
Min, Max	0.0, 20.8	0.0, 25.5	5.9, 12.1	0.0, 25.4	
C6D1 CFB					
n	58	109	4	9	
LS Mean (StdErr) [2]	-3.17 (0.660)	-3.88 (0.509)	2.19 (3.908)	1.34 (3.097)	
95% CI [2]	-4.47, -1.86	-4.89, -2.88	-6.65, 11.03	-5.67, 8.35	
Difference (95% CI) in CFB [2]		-0.71 (-2.17, 0.74)		-0.85 (-8.48, 6.77)	
p-value [3]		0.334		0.806	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.7a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	59	106	3	9	
Mean (StdDev)	7.68 (6.411)	6.17 (5.538)	8.43 (2.536)	7.42 (7.253)	
Median	6.08	4.89	9.86	4.64	
Min, Max	0.0, 22.9	0.0, 26.4	5.5, 9.9	0.4, 23.9	
C7D1 CFB					
n	59	106	3	9	
LS Mean (StdErr) [2]	-2.95 (0.697)	-3.76 (0.546)	1.52 (4.258)	0.10 (3.098)	
95% CI [2]	-4.32, -1.57	-4.83, -2.68	-8.30, 11.34	-7.04, 7.25	
Difference (95% CI) in CFB [2]		-0.81 (-2.35, 0.73)		-1.41 (-9.66, 6.83)	
Hedges'G (95% CI) in CFB		-0.15 (-0.47, 0.17)		-0.15 (-1.67, 1.30)	
p-value [3]		0.301		0.703	
					0.952

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.7a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	63	114	4	9	
Mean (StdDev)	18.30 (6.806)	16.20 (6.702)	12.27 (10.922)	18.82 (6.869)	
Median	18.79	16.17	11.82	18.64	
Min, Max	1.1, 30.0	1.9, 30.0	0.0, 25.4	8.8, 28.9	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.7a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	63	110	4	9	
Mean (StdDev)	16.61 (6.961)	13.55 (5.902)	11.39 (9.060)	15.44 (7.237)	
Median	16.50	13.00	12.50	14.43	
Min, Max	2.3, 29.8	0.0, 27.4	0.0, 20.6	4.6, 28.5	
C2D1 CFB					
n	63	110	4	9	
LS Mean (StdErr) [2]	-1.71 (0.484)	-2.72 (0.392)	0.85 (3.273)	-1.56 (2.594)	
95% CI [2]	-2.67, -0.76	-3.50, -1.95	-6.56, 8.25	-7.43, 4.31	
Difference (95% CI) in CFB [2]		-1.01 (-2.08, 0.07)		-2.41 (-8.79, 3.98)	
p-value [3]		0.065		0.416	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.7a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	63	108	4	9	
Mean (StdDev)	16.13 (7.228)	11.80 (5.897)	10.23 (7.930)	14.90 (7.735)	
Median	16.21	11.25	12.11	15.31	
Min, Max	2.0, 29.4	0.1, 25.4	0.0, 16.7	4.0, 28.1	
C3D1 CFB					
n	63	108	4	9	
LS Mean (StdErr) [2]	-1.82 (0.615)	-4.15 (0.499)	0.78 (3.865)	-0.95 (3.062)	
95% CI [2]	-3.04, -0.61	-5.14, -3.17	-7.96, 9.52	-7.88, 5.98	
Difference (95% CI) in CFB [2]		-2.33 (-3.70, -0.96)		-1.73 (-9.27, 5.81)	
p-value [3]		<0.001		0.616	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.7a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	60	108	4	9	
Mean (StdDev)	15.95 (7.346)	11.12 (6.008)	9.82 (7.975)	14.10 (7.952)	
Median	16.15	10.50	10.25	12.36	
Min, Max	2.8, 29.7	0.0, 24.5	0.0, 18.8	4.7, 28.6	
C4D1 CFB					
n	60	108	4	9	
LS Mean (StdErr) [2]	-2.06 (0.680)	-4.87 (0.538)	0.70 (4.940)	-0.76 (3.914)	
95% CI [2]	-3.40, -0.72	-5.94, -3.81	-10.48, 11.87	-9.62, 8.09	
Difference (95% CI) in CFB [2]		-2.82 (-4.31, -1.32)		-1.46 (-11.10, 8.18)	
p-value [3]		<0.001		0.740	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.7a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	59	110	4	9	
Mean (StdDev)	16.08 (7.297)	10.42 (5.810)	8.83 (6.803)	13.82 (8.702)	
Median	16.50	9.89	9.89	9.86	
Min, Max	1.4, 30.0	0.1, 25.2	0.0, 15.5	2.9, 28.5	
C5D1 CFB					
n	59	110	4	9	
LS Mean (StdErr) [2]	-1.96 (0.736)	-5.48 (0.569)	1.28 (5.218)	0.02 (4.135)	
95% CI [2]	-3.42, -0.51	-6.60, -4.36	-10.53, 13.08	-9.34, 9.37	
Difference (95% CI) in CFB [2]		-3.52 (-5.13, -1.90)		-1.26 (-11.44, 8.92)	
p-value [3]		<0.0001		0.786	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.7a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	58	109	4	9	
Mean (StdDev)	15.93 (7.311)	10.11 (6.096)	8.66 (6.413)	12.61 (8.673)	
Median	16.44	9.71	10.32	8.80	
Min, Max	1.6, 30.0	0.1, 29.4	0.0, 14.0	2.4, 30.0	
C6D1 CFB					
n	58	109	4	9	
LS Mean (StdErr) [2]	-2.18 (0.820)	-5.82 (0.632)	1.59 (4.306)	-0.57 (3.412)	
95% CI [2]	-3.80, -0.56	-7.06, -4.57	-8.16, 11.33	-8.29, 7.15	
Difference (95% CI) in CFB [2]		-3.63 (-5.44, -1.83)		-2.15 (-10.56, 6.25)	
p-value [3]		<0.001		0.576	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.7a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	59	106	3	9	
Mean (StdDev)	15.86 (7.167)	9.74 (6.053)	12.12 (4.631)	12.62 (9.111)	
Median	15.46	8.42	11.57	7.93	
Min, Max	1.2, 30.0	0.0, 28.9	7.8, 17.0	2.9, 30.0	
C7D1 CFB					
n	59	106	3	9	
LS Mean (StdErr) [2]	-2.19 (0.832)	-6.07 (0.652)	1.39 (5.768)	-1.09 (4.197)	
95% CI [2]	-3.83, -0.55	-7.36, -4.78	-11.91, 14.69	-10.77, 8.58	
Difference (95% CI) in CFB [2]		-3.88 (-5.72, -2.04)		-2.48 (-13.66, 8.69)	
Hedges'G (95% CI) in CFB		-0.59 (-0.92, -0.27)		-0.19 (-1.73, 1.25)	
p-value [3]		<0.0001		0.622	
					0.585

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.7a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	63	114	4	9	
Mean (StdDev)	13.16 (6.958)	13.84 (6.377)	13.64 (5.529)	15.30 (7.856)	
Median	12.50	13.63	12.61	15.07	
Min, Max	0.4, 29.1	1.9, 28.6	8.1, 21.3	2.4, 29.6	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.7a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	63	110	4	9	
Mean (StdDev)	11.79 (6.856)	11.89 (6.411)	12.38 (3.249)	14.08 (8.728)	
Median	10.14	10.81	11.25	11.79	
Min, Max	0.2, 27.4	0.0, 28.1	9.9, 17.1	3.0, 30.0	
C2D1 CFB					
n	63	110	4	9	
LS Mean (StdErr) [2]	-1.31 (0.426)	-1.95 (0.344)	-0.11 (2.596)	-0.60 (2.057)	
95% CI [2]	-2.15, -0.47	-2.63, -1.27	-5.98, 5.76	-5.25, 4.06	
Difference (95% CI) in CFB [2]		-0.64 (-1.58, 0.30)		-0.49 (-5.55, 4.58)	
p-value [3]		0.182		0.832	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.7a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	63	108	4	9	
Mean (StdDev)	10.87 (6.693)	10.76 (6.354)	12.02 (2.573)	13.05 (9.352)	
Median	9.14	9.57	12.39	11.93	
Min, Max	0.1, 27.3	0.0, 27.1	8.6, 14.7	1.5, 30.0	
C3D1 CFB					
n	63	108	4	9	
LS Mean (StdErr) [2]	-2.07 (0.533)	-2.93 (0.432)	0.52 (3.520)	-0.73 (2.789)	
95% CI [2]	-3.12, -1.02	-3.78, -2.07	-7.44, 8.49	-7.04, 5.58	
Difference (95% CI) in CFB [2]		-0.85 (-2.04, 0.33)		-1.25 (-8.12, 5.62)	
p-value [3]		0.157		0.690	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.7a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	60	108	4	9	
Mean (StdDev)	10.92 (6.682)	10.30 (6.436)	11.71 (1.713)	13.11 (9.516)	
Median	9.79	9.01	11.93	12.15	
Min, Max	0.0, 25.6	0.0, 26.6	9.6, 13.4	0.7, 29.9	
C4D1 CFB					
n	60	108	4	9	
LS Mean (StdErr) [2]	-2.11 (0.645)	-3.39 (0.510)	0.25 (3.855)	-0.53 (3.054)	
95% CI [2]	-3.38, -0.84	-4.40, -2.38	-8.47, 8.97	-7.44, 6.38	
Difference (95% CI) in CFB [2]		-1.28 (-2.70, 0.13)		-0.78 (-8.30, 6.75)	
p-value [3]		0.075		0.820	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.7a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	59	110	4	9	
Mean (StdDev)	10.67 (6.826)	9.89 (6.181)	11.27 (3.849)	13.87 (10.518)	
Median	9.64	8.34	13.15	13.69	
Min, Max	0.1, 26.2	0.0, 25.8	5.5, 13.3	0.5, 30.0	
C5D1 CFB					
n	59	110	4	9	
LS Mean (StdErr) [2]	-2.27 (0.633)	-3.64 (0.489)	2.27 (4.645)	1.34 (3.680)	
95% CI [2]	-3.52, -1.02	-4.60, -2.67	-8.24, 12.78	-6.98, 9.67	
Difference (95% CI) in CFB [2]		-1.36 (-2.75, 0.03)		-0.92 (-9.99, 8.14)	
p-value [3]		0.055		0.823	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.7a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	58	109	4	9	
Mean (StdDev)	10.19 (6.434)	9.23 (6.357)	12.09 (2.367)	12.34 (10.658)	
Median	8.59	7.75	12.39	10.07	
Min, Max	0.0, 25.0	0.0, 29.6	9.0, 14.6	0.1, 30.0	
C6D1 CFB					
n	58	109	4	9	
LS Mean (StdErr) [2]	-2.59 (0.678)	-4.23 (0.522)	3.09 (3.833)	0.28 (3.037)	
95% CI [2]	-3.93, -1.26	-5.26, -3.20	-5.58, 11.76	-6.59, 7.15	
Difference (95% CI) in CFB [2]		-1.64 (-3.13, -0.14)		-2.81 (-10.29, 4.67)	
p-value [3]		0.032		0.417	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.7a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	59	106	3	9	
Mean (StdDev)	10.25 (6.662)	9.14 (6.371)	13.00 (0.311)	12.36 (10.383)	
Median	8.58	8.30	12.86	9.86	
Min, Max	0.0, 23.4	0.0, 29.0	12.8, 13.4	0.7, 30.0	
C7D1 CFB					
n	59	106	3	9	
LS Mean (StdErr) [2]	-2.62 (0.685)	-4.27 (0.537)	3.00 (4.844)	0.02 (3.524)	
95% CI [2]	-3.98, -1.27	-5.33, -3.21	-8.17, 14.17	-8.11, 8.15	
Difference (95% CI) in CFB [2]		-1.64 (-3.16, -0.13)		-2.98 (-12.36, 6.41)	
Hedges'G (95% CI) in CFB		-0.30 (-0.63, 0.02)		-0.27 (-1.83, 1.15)	
p-value [3]		0.034		0.485	
					0.997

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.8a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	64	113	
Mean (StdDev)	8.60 (8.643)	13.21 (6.683)	11.00 (6.710)	10.18 (5.957)	
Median	3.86	12.75	10.11	9.14	
Min, Max	3.4, 18.6	2.9, 26.3	0.0, 28.0	0.1, 26.8	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.8a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	64	109	
Mean (StdDev)	7.83 (7.804)	11.56 (6.134)	8.89 (6.333)	8.20 (5.768)	
Median	5.07	12.07	7.75	7.21	
Min, Max	1.8, 16.6	1.0, 19.9	0.0, 26.4	0.0, 24.0	
C2D1 CFB					
n	3	10	64	109	
LS Mean (StdErr) [2]	0.12 (2.360)	0.14 (2.087)	-1.95 (0.402)	-1.84 (0.326)	
95% CI [2]	-5.22, 5.46	-4.58, 4.86	-2.74, -1.15	-2.48, -1.19	
Difference (95% CI) in CFB [2]		0.02 (-6.08, 6.12)		0.11 (-0.78, 1.00)	
p-value [3]		0.995		0.805	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.8a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	8	64	109	
Mean (StdDev)	5.87 (5.740)	8.74 (5.299)	8.28 (6.355)	7.45 (5.629)	
Median	2.62	7.11	7.24	6.57	
Min, Max	2.5, 12.5	2.7, 17.9	0.0, 23.9	0.0, 24.0	
C3D1 CFB					
n	3	8	64	109	
LS Mean (StdErr) [2]	-2.30 (2.371)	-3.29 (2.094)	-2.45 (0.534)	-2.46 (0.434)	
95% CI [2]	-7.90, 3.31	-8.24, 1.67	-3.50, -1.39	-3.32, -1.60	
Difference (95% CI) in CFB [2]		-0.99 (-7.43, 5.46)		-0.01 (-1.19, 1.16)	
p-value [3]		0.728		0.981	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.8a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	3	9	61	108	
Mean (StdDev)	6.10 (8.047)	8.08 (5.242)	8.54 (6.154)	6.82 (5.742)	
Median	1.69	7.50	7.57	5.59	
Min, Max	1.2, 15.4	0.1, 19.2	0.0, 23.5	0.0, 24.8	
C4D1 CFB					
n	3	9	61	108	
LS Mean (StdErr) [2]	-2.70 (2.756)	-5.69 (2.436)	-2.42 (0.623)	-3.06 (0.495)	
95% CI [2]	-9.05, 3.66	-11.31, -0.08	-3.65, -1.19	-4.03, -2.08	
Difference (95% CI) in CFB [2]		-3.00 (-10.28, 4.28)		-0.64 (-2.00, 0.72)	
p-value [3]		0.370		0.355	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.8a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	9	60	110	
Mean (StdDev)	5.58 (6.119)	6.61 (4.599)	8.65 (5.953)	6.71 (5.980)	
Median	2.57	6.38	7.52	5.71	
Min, Max	1.5, 12.6	0.0, 16.2	0.0, 23.3	0.0, 25.0	
C5D1 CFB					
n	3	9	60	110	
LS Mean (StdErr) [2]	-2.90 (2.814)	-6.47 (2.488)	-2.41 (0.678)	-3.18 (0.525)	
95% CI [2]	-9.39, 3.59	-12.21, -0.73	-3.75, -1.07	-4.21, -2.14	
Difference (95% CI) in CFB [2]		-3.57 (-11.00, 3.87)		-0.76 (-2.24, 0.71)	
p-value [3]		0.301		0.308	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.8a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	59	109	
Mean (StdDev)	5.35 (7.110)	6.22 (4.623)	7.56 (5.904)	6.26 (5.770)	
Median	1.71	6.21	6.07	5.00	
Min, Max	0.8, 13.5	0.0, 16.6	0.0, 20.8	0.0, 25.5	
C6D1 CFB					
n	3	9	59	109	
LS Mean (StdErr) [2]	-3.62 (3.051)	-7.81 (2.697)	-3.01 (0.665)	-3.45 (0.514)	
95% CI [2]	-10.66, 3.42	-14.03, -1.59	-4.33, -1.70	-4.47, -2.44	
Difference (95% CI) in CFB [2]		-4.19 (-12.25, 3.87)		-0.44 (-1.90, 1.01)	
p-value [3]		0.265		0.551	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.8a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	9	59	106	
Mean (StdDev)	6.03 (5.327)	7.04 (5.388)	7.80 (6.341)	6.20 (5.704)	
Median	5.21	5.43	6.36	4.84	
Min, Max	1.2, 11.7	0.0, 18.1	0.0, 22.9	0.0, 26.4	
C7D1 CFB					
n	3	9	59	106	
LS Mean (StdErr) [2]	-2.87 (3.661)	-6.95 (3.236)	-2.86 (0.699)	-3.47 (0.546)	
95% CI [2]	-11.31, 5.57	-14.41, 0.52	-4.24, -1.48	-4.55, -2.39	
Difference (95% CI) in CFB [2]		-4.07 (-13.74, 5.60)		-0.61 (-2.14, 0.92)	
Hedges'G (95% CI) in CFB		-0.41 (-2.02, 0.98)		-0.11 (-0.43, 0.21)	
p-value [3]		0.360		0.435	
					0.391

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.8a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	64	113	
Mean (StdDev)	21.95 (4.670)	19.53 (8.401)	17.75 (7.207)	16.11 (6.524)	
Median	21.07	20.46	18.32	16.17	
Min, Max	17.8, 27.0	3.3, 29.6	0.0, 30.0	1.9, 30.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.8a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	64	109	
Mean (StdDev)	21.38 (4.878)	16.57 (6.640)	16.06 (7.154)	13.43 (5.899)	
Median	20.86	17.43	16.37	13.00	
Min, Max	16.8, 26.5	3.3, 25.9	0.0, 29.8	0.0, 28.5	
C2D1 CFB					
n	3	10	64	109	
LS Mean (StdErr) [2]	-0.43 (2.392)	-2.54 (2.116)	-1.69 (0.493)	-2.73 (0.400)	
95% CI [2]	-5.84, 4.98	-7.33, 2.24	-2.67, -0.72	-3.52, -1.94	
Difference (95% CI) in CFB [2]		-2.11 (-8.30, 4.07)		-1.04 (-2.12, 0.05)	
p-value [3]		0.459		0.061	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.8a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	8	64	109	
Mean (StdDev)	19.67 (2.497)	14.25 (6.533)	15.59 (7.453)	11.87 (6.039)	
Median	21.00	12.07	15.68	11.31	
Min, Max	16.8, 21.2	4.4, 24.1	0.0, 29.4	0.1, 28.1	
C3D1 CFB					
n	3	8	64	109	
LS Mean (StdErr) [2]	-1.31 (3.979)	-4.77 (3.513)	-1.84 (0.609)	-3.97 (0.494)	
95% CI [2]	-10.72, 8.10	-13.08, 3.53	-3.05, -0.64	-4.95, -3.00	
Difference (95% CI) in CFB [2]		-3.47 (-14.28, 7.35)		-2.13 (-3.47, -0.79)	
p-value [3]		0.473		0.002	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.8a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	3	9	61	108	
Mean (StdDev)	19.89 (3.155)	11.99 (6.210)	15.36 (7.568)	11.30 (6.213)	
Median	21.23	10.93	15.79	10.64	
Min, Max	16.3, 22.2	3.9, 24.0	0.0, 29.7	0.0, 28.6	
C4D1 CFB					
n	3	9	61	108	
LS Mean (StdErr) [2]	-1.11 (4.292)	-6.04 (3.793)	-2.05 (0.680)	-4.57 (0.540)	
95% CI [2]	-11.01, 8.79	-14.79, 2.70	-3.39, -0.71	-5.64, -3.50	
Difference (95% CI) in CFB [2]		-4.93 (-16.27, 6.41)		-2.52 (-4.00, -1.04)	
p-value [3]		0.345		<0.001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.8a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	9	60	110	
Mean (StdDev)	19.21 (4.886)	11.28 (6.515)	15.44 (7.519)	10.63 (6.087)	
Median	21.23	10.36	15.99	9.82	
Min, Max	13.6, 22.8	4.4, 23.2	0.0, 30.0	0.1, 28.5	
C5D1 CFB					
n	3	9	60	110	
LS Mean (StdErr) [2]	-2.48 (4.663)	-7.89 (4.122)	-1.92 (0.736)	-5.07 (0.570)	
95% CI [2]	-13.23, 8.28	-17.40, 1.62	-3.37, -0.46	-6.20, -3.95	
Difference (95% CI) in CFB [2]		-5.41 (-17.73, 6.91)		-3.16 (-4.76, -1.56)	
p-value [3]		0.341		<0.001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.8a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	59	109	
Mean (StdDev)	17.92 (4.634)	10.38 (5.729)	15.34 (7.550)	10.29 (6.386)	
Median	20.50	8.71	15.67	9.71	
Min, Max	12.6, 20.7	3.8, 20.5	0.0, 30.0	0.1, 30.0	
C6D1 CFB					
n	3	9	59	109	
LS Mean (StdErr) [2]	-3.85 (4.594)	-8.97 (4.061)	-2.04 (0.807)	-5.40 (0.624)	
95% CI [2]	-14.44, 6.75	-18.33, 0.39	-3.63, -0.44	-6.63, -4.16	
Difference (95% CI) in CFB [2]		-5.12 (-17.26, 7.02)		-3.36 (-5.13, -1.59)	
p-value [3]		0.359		<0.001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.8a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin Domain Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	9	59	106	
Mean (StdDev)	18.87 (3.863)	10.08 (5.903)	15.52 (7.192)	9.95 (6.400)	
Median	20.71	9.21	15.21	8.32	
Min, Max	14.4, 21.5	3.5, 20.6	1.2, 30.0	0.0, 30.0	
C7D1 CFB					
n	3	9	59	106	
LS Mean (StdErr) [2]	-2.84 (4.608)	-9.15 (4.073)	-2.11 (0.835)	-5.64 (0.652)	
95% CI [2]	-13.47, 7.78	-18.55, 0.24	-3.76, -0.46	-6.93, -4.36	
Difference (95% CI) in CFB [2]		-6.31 (-18.48, 5.86)		-3.53 (-5.36, -1.71)	
Hedges'G (95% CI) in CFB		-0.51 (-2.14, 0.87)		-0.53 (-0.87, -0.21)	
p-value [3]		0.266		<0.001	
					0.482

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.8a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	64	113	
Mean (StdDev)	13.10 (9.424)	15.60 (7.022)	13.20 (6.804)	13.80 (6.432)	
Median	18.43	15.61	12.43	13.57	
Min, Max	2.2, 18.6	2.2, 26.0	0.4, 29.1	1.9, 29.6	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.8a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	64	109	
Mean (StdDev)	10.43 (8.616)	14.41 (6.743)	11.89 (6.657)	11.84 (6.569)	
Median	11.79	15.18	10.19	10.62	
Min, Max	1.2, 18.3	1.9, 25.9	0.2, 27.4	0.0, 30.0	
C2D1 CFB					
n	3	10	64	109	
LS Mean (StdErr) [2]	-3.10 (1.026)	-1.95 (0.907)	-1.19 (0.438)	-1.91 (0.356)	
95% CI [2]	-5.42, -0.78	-4.00, 0.11	-2.06, -0.33	-2.62, -1.21	
Difference (95% CI) in CFB [2]		1.16 (-1.49, 3.81)		-0.72 (-1.69, 0.24)	
p-value [3]		0.349		0.141	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.8a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	8	64	109	
Mean (StdDev)	10.98 (9.437)	14.21 (6.741)	10.93 (6.454)	10.70 (6.564)	
Median	14.43	15.89	9.24	9.54	
Min, Max	0.3, 18.2	3.5, 25.0	0.1, 27.3	0.0, 30.0	
C3D1 CFB					
n	3	8	64	109	
LS Mean (StdErr) [2]	-2.51 (1.843)	-2.54 (1.627)	-2.00 (0.549)	-2.90 (0.446)	
95% CI [2]	-6.87, 1.85	-6.39, 1.31	-3.09, -0.92	-3.78, -2.02	
Difference (95% CI) in CFB [2]		-0.03 (-5.04, 4.98)		-0.90 (-2.11, 0.31)	
p-value [3]		0.989		0.145	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.8a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	3	9	61	108	
Mean (StdDev)	8.88 (9.083)	11.67 (6.574)	11.07 (6.412)	10.42 (6.742)	
Median	8.50	9.29	9.93	9.29	
Min, Max	0.0, 18.2	2.1, 24.6	0.6, 25.6	0.0, 29.9	
C4D1 CFB					
n	3	9	61	108	
LS Mean (StdErr) [2]	-5.36 (2.295)	-5.89 (2.029)	-1.87 (0.654)	-3.13 (0.519)	
95% CI [2]	-10.65, -0.07	-10.56, -1.21	-3.17, -0.58	-4.16, -2.11	
Difference (95% CI) in CFB [2]		-0.53 (-6.59, 5.54)		-1.26 (-2.68, 0.17)	
p-value [3]		0.846		0.083	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.8a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	9	60	110	
Mean (StdDev)	8.23 (8.880)	10.39 (6.311)	10.83 (6.602)	10.17 (6.679)	
Median	6.93	8.46	9.96	8.71	
Min, Max	0.1, 17.7	1.8, 24.5	0.5, 26.2	0.0, 30.0	
C5D1 CFB					
n	3	9	60	110	
LS Mean (StdErr) [2]	-6.19 (2.015)	-7.41 (1.781)	-2.02 (0.665)	-3.20 (0.516)	
95% CI [2]	-10.83, -1.54	-11.52, -3.31	-3.33, -0.70	-4.21, -2.18	
Difference (95% CI) in CFB [2]		-1.23 (-6.55, 4.10)		-1.18 (-2.63, 0.27)	
p-value [3]		0.609		0.109	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.8a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	59	109	
Mean (StdDev)	8.02 (9.059)	9.49 (6.433)	10.43 (6.171)	9.47 (6.820)	
Median	6.21	8.71	9.00	7.75	
Min, Max	0.0, 17.8	1.6, 23.4	0.1, 25.0	0.0, 30.0	
C6D1 CFB					
n	3	9	59	109	
LS Mean (StdErr) [2]	-6.72 (2.652)	-8.84 (2.344)	-2.21 (0.681)	-3.80 (0.527)	
95% CI [2]	-12.83, -0.60	-14.25, -3.44	-3.56, -0.87	-4.84, -2.76	
Difference (95% CI) in CFB [2]		-2.13 (-9.13, 4.88)		-1.58 (-3.07, -0.09)	
p-value [3]		0.504		0.038	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.2.2.8a
Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	9	59	106	
Mean (StdDev)	7.93 (8.473)	9.96 (6.870)	10.51 (6.477)	9.34 (6.782)	
Median	6.93	8.27	9.29	8.54	
Min, Max	0.0, 16.9	1.9, 24.7	0.0, 23.4	0.0, 30.0	
C7D1 CFB					
n	3	9	59	106	
LS Mean (StdErr) [2]	-6.40 (3.052)	-7.56 (2.698)	-2.21 (0.696)	-3.88 (0.543)	
95% CI [2]	-13.44, 0.64	-13.79, -1.34	-3.59, -0.84	-4.95, -2.81	
Difference (95% CI) in CFB [2]		-1.16 (-9.23, 6.90)		-1.66 (-3.19, -0.14)	
Hedges'G (95% CI) in CFB		-0.14 (-1.66, 1.31)		-0.30 (-0.63, 0.02)	
p-value [3]		0.748		0.032	
					0.620

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	56	117	11	6	
Mean (StdDev)	5.92 (2.254)	5.58 (2.445)	3.65 (2.432)	6.12 (1.315)	
Median	5.93	6.00	3.43	5.73	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 7.0	4.9, 8.4	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	56	113	11	6	
Mean (StdDev)	5.16 (2.545)	4.84 (2.606)	3.82 (2.574)	5.14 (1.970)	
Median	5.39	5.07	3.50	5.02	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 7.9	2.6, 7.7	
C2D1 CFB					
n	56	113	11	6	
LS Mean (StdErr) [2]	-0.70 (0.192)	-0.71 (0.145)	0.13 (0.387)	-1.04 (0.565)	
95% CI [2]	-1.07, -0.32	-1.00, -0.43	-0.71, 0.96	-2.26, 0.18	
Difference (95% CI) in CFB [2]		-0.02 (-0.43, 0.40)		-1.16 (-2.11, -0.21)	
p-value [3]		0.943		0.020	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	56	111	11	6	
Mean (StdDev)	5.17 (2.539)	4.56 (2.717)	3.17 (2.690)	4.05 (1.962)	
Median	5.44	4.29	2.86	4.46	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 6.9	1.6, 6.7	
C3D1 CFB					
n	56	111	11	6	
LS Mean (StdErr) [2]	-0.73 (0.224)	-1.02 (0.169)	-0.19 (0.648)	-1.57 (0.944)	
95% CI [2]	-1.18, -0.29	-1.35, -0.68	-1.59, 1.21	-3.61, 0.47	
Difference (95% CI) in CFB [2]		-0.28 (-0.77, 0.20)		-1.38 (-2.97, 0.20)	
p-value [3]		0.250		0.082	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	54	111	10	6	
Mean (StdDev)	5.18 (2.636)	4.59 (2.828)	3.07 (2.710)	3.21 (1.667)	
Median	5.45	4.21	2.39	2.75	
Min, Max	0.0, 9.8	0.0, 10.0	0.0, 6.8	1.5, 5.8	
C4D1 CFB					
n	54	111	10	6	
LS Mean (StdErr) [2]	-0.67 (0.268)	-0.92 (0.199)	-0.34 (0.845)	-2.40 (1.222)	
95% CI [2]	-1.20, -0.14	-1.31, -0.52	-2.18, 1.50	-5.07, 0.26	
Difference (95% CI) in CFB [2]		-0.24 (-0.82, 0.33)		-2.06 (-4.14, 0.02)	
p-value [3]		0.404		0.052	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	54	113	9	6	
Mean (StdDev)	5.18 (2.606)	4.35 (2.825)	2.87 (2.759)	2.50 (1.851)	
Median	5.25	4.38	2.29	2.39	
Min, Max	0.0, 9.8	0.0, 10.0	0.0, 7.1	0.0, 4.6	
C5D1 CFB					
n	54	113	9	6	
LS Mean (StdErr) [2]	-0.62 (0.278)	-1.07 (0.203)	-0.40 (1.080)	-3.28 (1.545)	
95% CI [2]	-1.17, -0.07	-1.47, -0.67	-2.77, 1.98	-6.68, 0.12	
Difference (95% CI) in CFB [2]		-0.45 (-1.05, 0.15)		-2.89 (-5.55, -0.22)	
p-value [3]		0.141		0.036	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	52	112	10	6	
Mean (StdDev)	5.12 (2.632)	4.21 (2.755)	3.19 (2.656)	2.11 (1.564)	
Median	5.48	4.11	3.18	2.14	
Min, Max	0.0, 9.6	0.0, 10.0	0.0, 7.0	0.0, 3.7	
C6D1 CFB					
n	52	112	10	6	
LS Mean (StdErr) [2]	-0.51 (0.286)	-1.16 (0.206)	-0.35 (0.951)	-3.87 (1.375)	
95% CI [2]	-1.08, 0.05	-1.56, -0.75	-2.42, 1.72	-6.87, -0.88	
Difference (95% CI) in CFB [2]		-0.64 (-1.26, -0.03)		-3.52 (-5.86, -1.19)	
p-value [3]		0.041		0.007	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	52	109	10	6	
Mean (StdDev)	5.01 (2.684)	4.13 (2.822)	3.39 (2.584)	1.94 (1.571)	
Median	5.39	3.64	4.11	1.64	
Min, Max	0.0, 9.4	0.0, 10.0	0.0, 6.9	0.0, 4.1	
C7D1 CFB					
n	52	109	10	6	
LS Mean (StdErr) [2]	-0.71 (0.299)	-1.21 (0.218)	-0.04 (0.880)	-3.35 (1.272)	
95% CI [2]	-1.30, -0.12	-1.64, -0.78	-1.95, 1.88	-6.12, -0.58	
Difference (95% CI) in CFB [2]		-0.50 (-1.14, 0.15)		-3.31 (-5.47, -1.15)	
Hedges'G (95% CI) in CFB		-0.22 (-0.56, 0.11)		-1.08 (-2.46, -0.07)	
p-value [3]		0.131		0.006	
					0.005

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	56	117	11	6	
Mean (StdDev)	4.56 (2.325)	4.16 (2.194)	2.20 (1.898)	4.16 (2.226)	
Median	4.39	4.00	1.86	4.43	
Min, Max	0.0, 9.6	0.0, 9.8	0.0, 5.7	0.6, 6.9	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	56	113	11	6	
Mean (StdDev)	3.67 (2.180)	3.38 (2.186)	1.92 (1.611)	3.24 (1.702)	
Median	3.63	3.07	1.36	3.71	
Min, Max	0.0, 8.9	0.0, 9.4	0.0, 4.6	1.0, 5.6	
C2D1 CFB					
n	56	113	11	6	
LS Mean (StdErr) [2]	-0.80 (0.176)	-0.72 (0.133)	-0.27 (0.454)	-0.99 (0.662)	
95% CI [2]	-1.15, -0.46	-0.98, -0.46	-1.25, 0.71	-2.41, 0.44	
Difference (95% CI) in CFB [2]		0.08 (-0.30, 0.46)		-0.71 (-1.82, 0.40)	
p-value [3]		0.671		0.190	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	56	111	11	6	
Mean (StdDev)	3.39 (2.246)	3.01 (2.188)	2.10 (1.863)	1.73 (1.738)	
Median	3.18	2.86	1.64	1.43	
Min, Max	0.0, 8.4	0.0, 8.3	0.0, 5.4	0.0, 4.4	
C3D1 CFB					
n	56	111	11	6	
LS Mean (StdErr) [2]	-1.03 (0.218)	-1.03 (0.165)	-0.37 (0.600)	-2.97 (0.875)	
95% CI [2]	-1.46, -0.59	-1.35, -0.70	-1.67, 0.92	-4.86, -1.08	
Difference (95% CI) in CFB [2]		-0.00 (-0.48, 0.47)		-2.59 (-4.06, -1.12)	
p-value [3]		0.994		0.002	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	54	111	10	6	
Mean (StdDev)	3.35 (2.235)	2.72 (2.220)	2.08 (1.514)	1.86 (1.702)	
Median	3.36	2.36	2.83	1.18	
Min, Max	0.0, 7.9	0.0, 9.1	0.0, 3.7	0.2, 4.1	
C4D1 CFB					
n	54	111	10	6	
LS Mean (StdErr) [2]	-1.12 (0.262)	-1.32 (0.195)	-0.69 (0.800)	-3.15 (1.156)	
95% CI [2]	-1.64, -0.60	-1.71, -0.94	-2.43, 1.05	-5.67, -0.63	
Difference (95% CI) in CFB [2]		-0.20 (-0.77, 0.36)		-2.46 (-4.42, -0.49)	
p-value [3]		0.478		0.018	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	54	113	9	6	
Mean (StdDev)	3.36 (2.232)	2.64 (2.313)	2.55 (1.938)	1.33 (1.325)	
Median	3.04	2.07	3.00	1.11	
Min, Max	0.0, 8.1	0.0, 9.4	0.0, 5.6	0.0, 3.3	
C5D1 CFB					
n	54	113	9	6	
LS Mean (StdErr) [2]	-1.09 (0.283)	-1.38 (0.206)	-0.03 (1.124)	-3.10 (1.608)	
95% CI [2]	-1.65, -0.53	-1.79, -0.97	-2.51, 2.44	-6.64, 0.44	
Difference (95% CI) in CFB [2]		-0.29 (-0.90, 0.32)		-3.07 (-5.84, -0.29)	
p-value [3]		0.345		0.033	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	52	112	10	6	
Mean (StdDev)	2.89 (2.164)	2.47 (2.300)	1.72 (1.388)	1.74 (1.605)	
Median	2.69	2.12	1.86	1.57	
Min, Max	0.0, 7.1	0.0, 9.6	0.0, 3.9	0.0, 3.6	
C6D1 CFB					
n	52	112	10	6	
LS Mean (StdErr) [2]	-1.35 (0.299)	-1.49 (0.216)	-0.55 (0.830)	-2.48 (1.201)	
95% CI [2]	-1.94, -0.76	-1.92, -1.07	-2.36, 1.26	-5.10, 0.13	
Difference (95% CI) in CFB [2]		-0.14 (-0.78, 0.51)		-1.93 (-3.97, 0.11)	
p-value [3]		0.674		0.061	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	52	109	10	6	
Mean (StdDev)	3.08 (2.357)	2.50 (2.245)	1.90 (1.839)	1.67 (1.828)	
Median	2.59	2.00	1.89	1.14	
Min, Max	0.0, 8.3	0.0, 9.4	0.0, 4.9	0.0, 4.5	
C7D1 CFB					
n	52	109	10	6	
LS Mean (StdErr) [2]	-1.24 (0.293)	-1.45 (0.213)	-0.99 (0.716)	-3.78 (1.035)	
95% CI [2]	-1.82, -0.66	-1.87, -1.03	-2.55, 0.57	-6.03, -1.52	
Difference (95% CI) in CFB [2]		-0.21 (-0.84, 0.42)		-2.79 (-4.54, -1.03)	
Hedges'G (95% CI) in CFB		-0.09 (-0.43, 0.24)		-1.11 (-2.51, -0.10)	
p-value [3]		0.517		0.005	
					0.119

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	56	117	11	6	
Mean (StdDev)	3.83 (2.439)	3.20 (2.515)	2.05 (2.136)	3.52 (2.861)	
Median	3.75	2.83	1.15	3.61	
Min, Max	0.0, 8.9	0.0, 9.0	0.0, 6.4	0.4, 6.7	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	56	113	11	6	
Mean (StdDev)	3.29 (2.410)	2.77 (2.363)	1.47 (1.332)	2.03 (2.368)	
Median	3.11	2.36	1.62	1.31	
Min, Max	0.0, 8.3	0.0, 8.8	0.0, 4.2	0.0, 6.2	
C2D1 CFB					
n	56	113	11	6	
LS Mean (StdErr) [2]	-0.42 (0.180)	-0.32 (0.136)	-2.49 (0.615)	-3.87 (0.897)	
95% CI [2]	-0.77, -0.06	-0.59, -0.06	-3.82, -1.16	-5.80, -1.93	
Difference (95% CI) in CFB [2]		0.09 (-0.30, 0.48)		-1.38 (-2.88, 0.13)	
p-value [3]		0.646		0.070	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	56	111	11	6	
Mean (StdDev)	2.88 (2.360)	2.46 (2.297)	1.49 (1.617)	1.81 (2.097)	
Median	2.47	2.00	1.08	1.00	
Min, Max	0.0, 7.7	0.0, 8.9	0.0, 4.9	0.0, 5.9	
C3D1 CFB					
n	56	111	11	6	
LS Mean (StdErr) [2]	-0.83 (0.218)	-0.63 (0.165)	-2.76 (0.772)	-4.32 (1.126)	
95% CI [2]	-1.26, -0.40	-0.96, -0.31	-4.43, -1.09	-6.75, -1.89	
Difference (95% CI) in CFB [2]		0.20 (-0.27, 0.68)		-1.56 (-3.45, 0.33)	
p-value [3]		0.402		0.098	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	54	111	10	6	
Mean (StdDev)	2.91 (2.321)	2.20 (2.271)	1.81 (1.383)	1.27 (1.660)	
Median	2.29	1.62	2.04	0.52	
Min, Max	0.0, 7.4	0.0, 9.2	0.0, 4.0	0.0, 4.1	
C4D1 CFB					
n	54	111	10	6	
LS Mean (StdErr) [2]	-0.91 (0.256)	-0.95 (0.190)	-2.07 (0.810)	-4.05 (1.172)	
95% CI [2]	-1.42, -0.41	-1.32, -0.57	-3.84, -0.31	-6.61, -1.50	
Difference (95% CI) in CFB [2]		-0.03 (-0.58, 0.52)		-1.98 (-3.97, 0.01)	
p-value [3]		0.905		0.051	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	54	113	9	6	
Mean (StdDev)	2.96 (2.288)	2.19 (2.277)	1.83 (1.396)	0.79 (1.055)	
Median	2.83	1.64	1.71	0.29	
Min, Max	0.0, 8.5	0.0, 8.9	0.0, 3.8	0.0, 2.4	
C5D1 CFB					
n	54	113	9	6	
LS Mean (StdErr) [2]	-0.83 (0.275)	-0.90 (0.201)	-2.44 (0.874)	-4.93 (1.250)	
95% CI [2]	-1.38, -0.29	-1.30, -0.51	-4.36, -0.52	-7.69, -2.18	
Difference (95% CI) in CFB [2]		-0.07 (-0.66, 0.52)		-2.49 (-4.65, -0.34)	
p-value [3]		0.812		0.027	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	52	112	10	6	
Mean (StdDev)	2.66 (2.177)	1.94 (2.197)	1.36 (1.286)	1.10 (1.867)	
Median	2.36	1.41	1.04	0.04	
Min, Max	0.0, 7.9	0.0, 9.9	0.0, 3.5	0.0, 4.6	
C6D1 CFB					
n	52	112	10	6	
LS Mean (StdErr) [2]	-1.10 (0.279)	-1.14 (0.201)	-2.98 (0.812)	-4.60 (1.175)	
95% CI [2]	-1.66, -0.55	-1.54, -0.74	-4.75, -1.21	-7.16, -2.04	
Difference (95% CI) in CFB [2]		-0.04 (-0.64, 0.57)		-1.63 (-3.62, 0.37)	
p-value [3]		0.909		0.101	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	52	109	10	6	
Mean (StdDev)	2.75 (2.314)	2.00 (2.211)	1.57 (1.796)	0.90 (1.300)	
Median	2.38	1.36	0.59	0.14	
Min, Max	0.0, 7.7	0.0, 9.5	0.0, 4.6	0.0, 2.8	
C7D1 CFB					
n	52	109	10	6	
LS Mean (StdErr) [2]	-0.99 (0.301)	-1.03 (0.219)	-3.06 (0.878)	-5.53 (1.270)	
95% CI [2]	-1.58, -0.39	-1.47, -0.60	-4.97, -1.14	-8.29, -2.76	
Difference (95% CI) in CFB [2]		-0.05 (-0.70, 0.60)		-2.47 (-4.63, -0.31)	
Hedges'G (95% CI) in CFB		-0.02 (-0.35, 0.31)		-0.80 (-2.10, 0.21)	
p-value [3]		0.885		0.028	
					0.165

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	56	117	11	6	
Mean (StdDev)	5.76 (2.992)	5.53 (3.007)	7.47 (2.854)	5.84 (3.475)	
Median	6.32	6.00	9.00	6.40	
Min, Max	0.0, 10.0	0.0, 10.0	2.2, 10.0	0.0, 9.3	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	56	113	11	6	
Mean (StdDev)	5.31 (2.754)	4.67 (2.716)	7.25 (2.963)	4.14 (3.755)	
Median	5.64	4.79	8.71	3.79	
Min, Max	0.0, 10.0	0.0, 10.0	2.1, 10.0	0.0, 9.0	
C2D1 CFB					
n	56	113	11	6	
LS Mean (StdErr) [2]	-0.36 (0.180)	-0.82 (0.136)	-0.17 (0.780)	-1.70 (1.137)	
95% CI [2]	-0.72, -0.01	-1.09, -0.55	-1.86, 1.51	-4.15, 0.76	
Difference (95% CI) in CFB [2]		-0.46 (-0.85, -0.06)		-1.53 (-3.44, 0.38)	
p-value [3]		0.023		0.108	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	56	111	11	6	
Mean (StdDev)	5.30 (2.830)	4.25 (2.598)	6.98 (3.065)	3.60 (2.891)	
Median	5.39	4.07	8.00	2.96	
Min, Max	0.0, 10.0	0.0, 9.8	1.1, 10.0	0.0, 8.1	
C3D1 CFB					
n	56	111	11	6	
LS Mean (StdErr) [2]	-0.23 (0.229)	-1.15 (0.173)	-0.76 (0.717)	-2.69 (1.046)	
95% CI [2]	-0.68, 0.22	-1.49, -0.81	-2.31, 0.79	-4.95, -0.43	
Difference (95% CI) in CFB [2]		-0.92 (-1.42, -0.43)		-1.93 (-3.69, -0.17)	
p-value [3]		<0.001		0.034	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	54	111	10	6	
Mean (StdDev)	5.23 (2.841)	4.05 (2.573)	6.95 (3.089)	2.80 (2.984)	
Median	5.33	3.86	7.50	2.58	
Min, Max	0.0, 10.0	0.0, 9.4	1.9, 10.0	0.0, 8.0	
C4D1 CFB					
n	54	111	10	6	
LS Mean (StdErr) [2]	-0.22 (0.238)	-1.25 (0.177)	-0.32 (0.942)	-3.08 (1.362)	
95% CI [2]	-0.69, 0.25	-1.60, -0.90	-2.38, 1.73	-6.04, -0.11	
Difference (95% CI) in CFB [2]		-1.03 (-1.54, -0.52)		-2.75 (-5.07, -0.44)	
p-value [3]		<0.001		0.024	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	54	113	9	6	
Mean (StdDev)	5.08 (2.838)	3.82 (2.535)	7.32 (2.742)	2.58 (3.204)	
Median	5.11	3.36	8.00	1.91	
Min, Max	0.0, 10.0	0.0, 9.9	3.3, 10.0	0.0, 8.6	
C5D1 CFB					
n	54	113	9	6	
LS Mean (StdErr) [2]	-0.42 (0.256)	-1.49 (0.187)	-0.34 (1.065)	-3.54 (1.524)	
95% CI [2]	-0.92, 0.09	-1.86, -1.12	-2.68, 2.01	-6.89, -0.19	
Difference (95% CI) in CFB [2]		-1.07 (-1.62, -0.52)		-3.20 (-5.83, -0.58)	
p-value [3]		<0.001		0.021	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	52	112	10	6	
Mean (StdDev)	5.26 (2.798)	3.66 (2.566)	6.61 (3.408)	2.36 (2.724)	
Median	5.00	3.31	7.36	1.86	
Min, Max	0.0, 10.0	0.0, 10.0	0.4, 10.0	0.0, 7.3	
C6D1 CFB					
n	52	112	10	6	
LS Mean (StdErr) [2]	-0.15 (0.305)	-1.55 (0.220)	-0.75 (1.011)	-3.83 (1.462)	
95% CI [2]	-0.76, 0.45	-1.98, -1.11	-2.96, 1.45	-7.02, -0.65	
Difference (95% CI) in CFB [2]		-1.39 (-2.05, -0.73)		-3.08 (-5.56, -0.59)	
p-value [3]		<0.0001		0.019	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	52	109	10	6	
Mean (StdDev)	5.25 (2.786)	3.64 (2.660)	6.83 (2.957)	2.24 (2.611)	
Median	5.00	3.29	7.23	1.82	
Min, Max	0.0, 10.0	0.0, 10.0	2.4, 10.0	0.0, 7.0	
C7D1 CFB					
n	52	109	10	6	
LS Mean (StdErr) [2]	-0.32 (0.317)	-1.63 (0.231)	-0.63 (0.966)	-3.92 (1.397)	
95% CI [2]	-0.95, 0.31	-2.09, -1.18	-2.74, 1.47	-6.97, -0.88	
Difference (95% CI) in CFB [2]		-1.32 (-2.00, -0.63)		-3.29 (-5.66, -0.91)	
Hedges'G (95% CI) in CFB		-0.55 (-0.90, -0.22)		-0.97 (-2.32, 0.04)	
p-value [3]		<0.001		0.011	
					0.188

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	56	117	11	6	
Mean (StdDev)	5.85 (2.629)	5.38 (2.668)	6.56 (2.756)	6.87 (2.681)	
Median	6.36	5.77	7.00	7.56	
Min, Max	0.0, 10.0	0.0, 10.0	1.9, 10.0	3.5, 9.6	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	56	113	11	6	
Mean (StdDev)	5.19 (2.607)	4.31 (2.364)	5.76 (3.438)	5.38 (2.416)	
Median	5.68	4.29	6.36	5.46	
Min, Max	0.0, 10.0	0.0, 9.9	0.5, 9.8	1.6, 8.6	
C2D1 CFB					
n	56	113	11	6	
LS Mean (StdErr) [2]	-0.68 (0.238)	-1.12 (0.180)	-0.44 (0.683)	-1.59 (0.996)	
95% CI [2]	-1.15, -0.21	-1.48, -0.77	-1.91, 1.04	-3.74, 0.56	
Difference (95% CI) in CFB [2]		-0.44 (-0.96, 0.07)		-1.16 (-2.83, 0.52)	
p-value [3]		0.093		0.160	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	56	111	11	6	
Mean (StdDev)	4.94 (2.692)	3.67 (2.447)	5.32 (3.080)	3.77 (2.543)	
Median	4.82	3.57	5.85	3.54	
Min, Max	0.0, 10.0	0.0, 9.7	0.0, 9.1	0.8, 8.0	
C3D1 CFB					
n	56	111	11	6	
LS Mean (StdErr) [2]	-0.75 (0.289)	-1.60 (0.218)	-0.96 (0.939)	-3.07 (1.369)	
95% CI [2]	-1.32, -0.18	-2.03, -1.17	-2.99, 1.07	-6.03, -0.11	
Difference (95% CI) in CFB [2]		-0.85 (-1.47, -0.22)		-2.11 (-4.41, 0.19)	
p-value [3]		0.008		0.070	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	54	111	10	6	
Mean (StdDev)	4.81 (2.757)	3.46 (2.552)	5.42 (3.132)	3.10 (2.572)	
Median	5.14	3.23	6.47	1.79	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 9.1	1.4, 8.0	
C4D1 CFB					
n	54	111	10	6	
LS Mean (StdErr) [2]	-1.01 (0.343)	-1.88 (0.255)	-0.79 (1.235)	-3.07 (1.785)	
95% CI [2]	-1.68, -0.33	-2.39, -1.38	-3.48, 1.90	-6.96, 0.82	
Difference (95% CI) in CFB [2]		-0.88 (-1.62, -0.14)		-2.28 (-5.31, 0.76)	
p-value [3]		0.020		0.128	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	54	113	9	6	
Mean (StdDev)	4.81 (2.627)	3.23 (2.512)	6.32 (2.586)	2.31 (2.661)	
Median	4.73	3.00	6.77	1.18	
Min, Max	0.0, 10.0	0.0, 10.0	2.2, 10.0	0.3, 7.5	
C5D1 CFB					
n	54	113	9	6	
LS Mean (StdErr) [2]	-0.93 (0.353)	-2.01 (0.258)	-0.45 (1.208)	-3.98 (1.728)	
95% CI [2]	-1.62, -0.23	-2.52, -1.50	-3.11, 2.21	-7.78, -0.17	
Difference (95% CI) in CFB [2]		-1.08 (-1.84, -0.32)		-3.53 (-6.50, -0.55)	
p-value [3]		0.005		0.024	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	52	112	10	6	
Mean (StdDev)	4.78 (2.597)	3.15 (2.558)	5.74 (3.051)	2.33 (2.307)	
Median	4.88	2.89	6.21	1.64	
Min, Max	0.0, 10.0	0.0, 10.0	0.1, 10.0	0.3, 6.6	
C6D1 CFB					
n	52	112	10	6	
LS Mean (StdErr) [2]	-1.02 (0.364)	-2.17 (0.262)	-0.64 (1.185)	-4.02 (1.713)	
95% CI [2]	-1.74, -0.30	-2.69, -1.65	-3.22, 1.94	-7.75, -0.29	
Difference (95% CI) in CFB [2]		-1.15 (-1.94, -0.36)		-3.38 (-6.29, -0.47)	
p-value [3]		0.004		0.027	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	52	109	10	6	
Mean (StdDev)	4.91 (2.503)	3.09 (2.513)	5.78 (2.821)	2.18 (2.398)	
Median	5.00	2.86	6.81	1.61	
Min, Max	0.0, 10.0	0.0, 10.0	1.8, 9.9	0.0, 6.6	
C7D1 CFB					
n	52	109	10	6	
LS Mean (StdErr) [2]	-0.99 (0.384)	-2.22 (0.279)	-0.40 (1.165)	-3.66 (1.684)	
95% CI [2]	-1.75, -0.24	-2.77, -1.67	-2.94, 2.14	-7.33, 0.01	
Difference (95% CI) in CFB [2]		-1.22 (-2.05, -0.39)		-3.26 (-6.12, -0.40)	
Hedges'G (95% CI) in CFB		-0.42 (-0.77, -0.09)		-0.80 (-2.10, 0.22)	
p-value [3]		0.004		0.029	
					0.113

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	56	117	11	6	
Mean (StdDev)	5.82 (2.530)	5.40 (2.405)	6.52 (2.703)	5.22 (2.705)	
Median	5.85	5.50	5.77	5.14	
Min, Max	0.0, 10.0	0.0, 10.0	3.3, 10.0	1.6, 8.9	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	56	113	11	6	
Mean (StdDev)	5.34 (2.475)	4.77 (2.415)	5.65 (3.457)	3.04 (2.987)	
Median	5.11	5.00	4.00	2.33	
Min, Max	0.0, 10.0	0.0, 10.0	1.4, 10.0	0.4, 8.2	
C2D1 CFB					
n	56	113	11	6	
LS Mean (StdErr) [2]	-0.48 (0.206)	-0.66 (0.156)	-0.60 (1.055)	-2.16 (1.538)	
95% CI [2]	-0.88, -0.07	-0.97, -0.35	-2.88, 1.68	-5.48, 1.16	
Difference (95% CI) in CFB [2]		-0.18 (-0.63, 0.27)		-1.56 (-4.15, 1.02)	
p-value [3]		0.425		0.215	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	56	111	11	6	
Mean (StdDev)	5.12 (2.679)	4.21 (2.471)	5.58 (3.447)	2.95 (3.089)	
Median	5.29	4.21	5.14	1.57	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 10.0	0.5, 8.0	
C3D1 CFB					
n	56	111	11	6	
LS Mean (StdErr) [2]	-0.58 (0.255)	-1.15 (0.193)	-0.60 (1.230)	-2.01 (1.794)	
95% CI [2]	-1.08, -0.07	-1.53, -0.76	-3.26, 2.06	-5.88, 1.87	
Difference (95% CI) in CFB [2]		-0.57 (-1.12, -0.01)		-1.41 (-4.43, 1.60)	
p-value [3]		0.045		0.330	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	54	111	10	6	
Mean (StdDev)	5.03 (2.748)	3.99 (2.485)	5.87 (3.423)	2.71 (3.199)	
Median	4.93	3.77	6.11	1.12	
Min, Max	0.0, 10.0	0.0, 10.0	0.2, 10.0	0.0, 8.0	
C4D1 CFB					
n	54	111	10	6	
LS Mean (StdErr) [2]	-0.73 (0.299)	-1.44 (0.222)	-0.68 (1.283)	-2.26 (1.855)	
95% CI [2]	-1.32, -0.13	-1.88, -1.00	-3.47, 2.11	-6.30, 1.78	
Difference (95% CI) in CFB [2]		-0.72 (-1.36, -0.08)		-1.58 (-4.73, 1.57)	
p-value [3]		0.029		0.297	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	54	113	9	6	
Mean (StdDev)	4.89 (2.797)	3.81 (2.517)	7.07 (2.498)	2.25 (2.782)	
Median	4.86	3.85	8.00	1.07	
Min, Max	0.0, 10.0	0.0, 9.8	3.9, 10.0	0.0, 7.2	
C5D1 CFB					
n	54	113	9	6	
LS Mean (StdErr) [2]	-0.93 (0.338)	-1.65 (0.247)	0.14 (0.903)	-2.61 (1.291)	
95% CI [2]	-1.60, -0.26	-2.13, -1.16	-1.84, 2.13	-5.45, 0.24	
Difference (95% CI) in CFB [2]		-0.72 (-1.44, 0.01)		-2.75 (-4.97, -0.52)	
p-value [3]		0.054		0.020	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	52	112	10	6	
Mean (StdDev)	4.80 (2.825)	3.68 (2.568)	6.35 (2.975)	2.10 (2.545)	
Median	5.00	3.58	6.39	1.21	
Min, Max	0.0, 10.0	0.0, 10.0	1.1, 10.0	0.0, 6.6	
C6D1 CFB					
n	52	112	10	6	
LS Mean (StdErr) [2]	-1.03 (0.354)	-1.79 (0.256)	-0.33 (1.034)	-2.90 (1.495)	
95% CI [2]	-1.73, -0.34	-2.29, -1.28	-2.58, 1.92	-6.16, 0.35	
Difference (95% CI) in CFB [2]		-0.75 (-1.52, 0.01)		-2.57 (-5.11, -0.03)	
p-value [3]		0.054		0.048	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	52	109	10	6	
Mean (StdDev)	4.86 (2.766)	3.43 (2.532)	6.44 (2.926)	2.07 (2.742)	
Median	4.95	3.17	6.69	1.04	
Min, Max	0.0, 10.0	0.0, 10.0	1.2, 10.0	0.0, 7.0	
C7D1 CFB					
n	52	109	10	6	
LS Mean (StdErr) [2]	-1.00 (0.369)	-1.90 (0.269)	-0.18 (1.078)	-2.83 (1.559)	
95% CI [2]	-1.73, -0.27	-2.43, -1.37	-2.53, 2.17	-6.23, 0.57	
Difference (95% CI) in CFB [2]		-0.91 (-1.71, -0.11)		-2.65 (-5.30, -0.00)	
Hedges'G (95% CI) in CFB		-0.33 (-0.67, 0.00)		-0.70 (-1.97, 0.32)	
p-value [3]		0.026		0.050	
					0.219

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	56	117	11	6	
Mean (StdDev)	7.03 (1.991)	6.94 (2.019)	5.53 (1.609)	7.03 (1.316)	
Median	6.93	7.21	5.93	6.86	
Min, Max	0.0, 10.0	0.1, 10.0	2.8, 8.0	5.2, 9.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	56	113	11	6	
Mean (StdDev)	6.52 (1.963)	6.25 (2.233)	5.61 (1.640)	6.61 (1.612)	
Median	6.43	6.38	6.21	6.18	
Min, Max	2.3, 10.0	0.1, 10.0	2.4, 8.3	4.6, 9.0	
C2D1 CFB					
n	56	113	11	6	
LS Mean (StdErr) [2]	-0.52 (0.187)	-0.72 (0.141)	-0.11 (0.358)	-0.73 (0.522)	
95% CI [2]	-0.89, -0.15	-1.00, -0.44	-0.88, 0.66	-1.86, 0.40	
Difference (95% CI) in CFB [2]		-0.21 (-0.61, 0.20)		-0.62 (-1.50, 0.26)	
p-value [3]		0.315		0.150	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	56	111	11	6	
Mean (StdDev)	6.13 (2.329)	5.81 (2.331)	5.57 (1.913)	5.90 (1.934)	
Median	6.00	5.79	6.00	6.14	
Min, Max	0.3, 10.0	0.2, 10.0	2.2, 8.0	3.1, 8.5	
C3D1 CFB					
n	56	111	11	6	
LS Mean (StdErr) [2]	-0.90 (0.238)	-1.12 (0.180)	-0.10 (0.730)	-1.49 (1.064)	
95% CI [2]	-1.37, -0.43	-1.48, -0.77	-1.68, 1.47	-3.78, 0.81	
Difference (95% CI) in CFB [2]		-0.22 (-0.74, 0.30)		-1.39 (-3.17, 0.40)	
p-value [3]		0.401		0.118	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	54	111	10	6	
Mean (StdDev)	5.97 (2.403)	5.59 (2.456)	5.09 (2.251)	4.16 (2.697)	
Median	5.88	5.58	6.00	4.64	
Min, Max	0.2, 10.0	0.4, 10.0	1.4, 7.8	0.0, 7.6	
C4D1 CFB					
n	54	111	10	6	
LS Mean (StdErr) [2]	-1.10 (0.277)	-1.38 (0.206)	-0.14 (1.457)	-2.69 (2.107)	
95% CI [2]	-1.65, -0.55	-1.79, -0.97	-3.31, 3.04	-7.28, 1.90	
Difference (95% CI) in CFB [2]		-0.28 (-0.88, 0.31)		-2.55 (-6.14, 1.03)	
p-value [3]		0.351		0.146	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	54	113	9	6	
Mean (StdDev)	5.83 (2.506)	5.59 (2.420)	5.00 (1.789)	3.34 (2.110)	
Median	5.61	5.69	5.71	4.00	
Min, Max	0.6, 10.0	0.1, 10.0	1.5, 7.4	0.0, 6.1	
C5D1 CFB					
n	54	113	9	6	
LS Mean (StdErr) [2]	-1.19 (0.289)	-1.33 (0.211)	-0.19 (1.253)	-3.50 (1.792)	
95% CI [2]	-1.76, -0.61	-1.75, -0.92	-2.95, 2.57	-7.44, 0.45	
Difference (95% CI) in CFB [2]		-0.15 (-0.77, 0.47)		-3.31 (-6.40, -0.22)	
p-value [3]		0.639		0.038	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	52	112	10	6	
Mean (StdDev)	5.89 (2.470)	5.32 (2.704)	5.33 (1.929)	3.06 (2.133)	
Median	5.96	5.29	5.32	3.79	
Min, Max	0.4, 10.0	0.0, 10.0	2.6, 8.4	0.0, 5.1	
C6D1 CFB					
n	52	112	10	6	
LS Mean (StdErr) [2]	-1.08 (0.314)	-1.57 (0.226)	0.08 (1.258)	-3.60 (1.818)	
95% CI [2]	-1.70, -0.46	-2.01, -1.12	-2.66, 2.82	-7.56, 0.37	
Difference (95% CI) in CFB [2]		-0.49 (-1.16, 0.19)		-3.67 (-6.77, -0.58)	
p-value [3]		0.159		0.024	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	52	109	10	6	
Mean (StdDev)	5.80 (2.612)	5.17 (2.614)	5.53 (1.817)	2.77 (1.968)	
Median	5.67	5.15	5.82	2.71	
Min, Max	0.2, 10.0	0.0, 10.0	2.8, 7.7	0.0, 5.4	
C7D1 CFB					
n	52	109	10	6	
LS Mean (StdErr) [2]	-1.15 (0.318)	-1.66 (0.231)	0.09 (1.168)	-4.41 (1.689)	
95% CI [2]	-1.78, -0.53	-2.12, -1.20	-2.46, 2.63	-8.09, -0.73	
Difference (95% CI) in CFB [2]		-0.51 (-1.19, 0.18)		-4.50 (-7.37, -1.62)	
Hedges'G (95% CI) in CFB		-0.21 (-0.55, 0.12)		-1.10 (-2.49, -0.09)	
p-value [3]		0.148		0.005	
					0.001

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	56	117	11	6	
Mean (StdDev)	4.00 (2.855)	4.03 (2.831)	2.27 (1.816)	2.61 (2.303)	
Median	3.26	4.21	2.31	2.83	
Min, Max	0.0, 9.3	0.0, 10.0	0.0, 5.1	0.0, 5.6	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	56	113	11	6	
Mean (StdDev)	3.43 (2.790)	3.45 (2.658)	2.07 (1.670)	1.79 (2.536)	
Median	2.96	3.07	2.43	0.44	
Min, Max	0.0, 8.7	0.0, 10.0	0.0, 4.8	0.0, 6.0	
C2D1 CFB					
n	56	113	11	6	
LS Mean (StdErr) [2]	-0.49 (0.209)	-0.57 (0.158)	-0.30 (0.591)	-1.62 (0.861)	
95% CI [2]	-0.90, -0.07	-0.88, -0.25	-1.58, 0.97	-3.48, 0.25	
Difference (95% CI) in CFB [2]		-0.08 (-0.53, 0.37)		-1.31 (-2.76, 0.14)	
p-value [3]		0.729		0.072	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	56	111	11	6	
Mean (StdDev)	3.14 (2.647)	3.06 (2.716)	1.59 (1.755)	1.27 (1.834)	
Median	2.52	2.43	1.57	0.50	
Min, Max	0.0, 8.1	0.0, 10.0	0.0, 4.4	0.0, 4.6	
C3D1 CFB					
n	56	111	11	6	
LS Mean (StdErr) [2]	-0.68 (0.240)	-0.88 (0.181)	-0.66 (0.752)	-2.25 (1.096)	
95% CI [2]	-1.16, -0.21	-1.24, -0.53	-2.28, 0.97	-4.62, 0.11	
Difference (95% CI) in CFB [2]		-0.20 (-0.72, 0.32)		-1.60 (-3.44, 0.24)	
p-value [3]		0.452		0.083	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	54	111	10	6	
Mean (StdDev)	3.27 (2.716)	2.98 (2.763)	1.88 (1.973)	1.25 (1.909)	
Median	2.89	2.23	1.52	0.58	
Min, Max	0.0, 9.9	0.0, 10.0	0.0, 5.4	0.0, 4.9	
C4D1 CFB					
n	54	111	10	6	
LS Mean (StdErr) [2]	-0.57 (0.294)	-0.97 (0.219)	-0.39 (0.892)	-2.05 (1.290)	
95% CI [2]	-1.16, 0.01	-1.40, -0.53	-2.33, 1.55	-4.86, 0.76	
Difference (95% CI) in CFB [2]		-0.39 (-1.02, 0.24)		-1.66 (-3.85, 0.53)	
p-value [3]		0.223		0.125	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	54	113	9	6	
Mean (StdDev)	3.22 (2.655)	2.83 (2.683)	2.11 (2.183)	0.83 (1.248)	
Median	2.37	2.07	2.31	0.15	
Min, Max	0.0, 9.6	0.0, 10.0	0.0, 5.3	0.0, 3.0	
C5D1 CFB					
n	54	113	9	6	
LS Mean (StdErr) [2]	-0.56 (0.290)	-1.03 (0.212)	-0.27 (0.662)	-2.55 (0.947)	
95% CI [2]	-1.13, 0.01	-1.45, -0.61	-1.73, 1.19	-4.63, -0.46	
Difference (95% CI) in CFB [2]		-0.46 (-1.09, 0.16)		-2.28 (-3.91, -0.64)	
p-value [3]		0.143		0.011	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	52	112	10	6	
Mean (StdDev)	3.07 (2.654)	2.54 (2.589)	1.76 (2.063)	0.77 (1.246)	
Median	1.96	1.96	1.11	0.00	
Min, Max	0.0, 8.6	0.0, 10.0	0.0, 4.9	0.0, 2.9	
C6D1 CFB					
n	52	112	10	6	
LS Mean (StdErr) [2]	-0.74 (0.311)	-1.28 (0.225)	-0.50 (0.707)	-2.66 (1.023)	
95% CI [2]	-1.35, -0.12	-1.72, -0.83	-2.04, 1.04	-4.89, -0.43	
Difference (95% CI) in CFB [2]		-0.54 (-1.21, 0.13)		-2.16 (-3.90, -0.42)	
p-value [3]		0.115		0.019	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	52	109	10	6	
Mean (StdDev)	3.03 (2.717)	2.58 (2.603)	2.02 (2.264)	0.45 (0.573)	
Median	2.04	2.00	1.21	0.18	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 5.6	0.0, 1.3	
C7D1 CFB					
n	52	109	10	6	
LS Mean (StdErr) [2]	-0.82 (0.324)	-1.24 (0.235)	-0.30 (0.895)	-2.90 (1.293)	
95% CI [2]	-1.46, -0.18	-1.71, -0.78	-2.25, 1.65	-5.72, -0.08	
Difference (95% CI) in CFB [2]		-0.42 (-1.12, 0.28)		-2.60 (-4.80, -0.40)	
Hedges'G (95% CI) in CFB		-0.17 (-0.51, 0.16)		-0.83 (-2.13, 0.19)	
p-value [3]		0.234		0.024	
					0.348

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	56	117	11	6	
Mean (StdDev)	5.70 (2.593)	5.69 (2.429)	2.84 (1.685)	5.29 (2.748)	
Median	5.79	5.79	3.07	6.04	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 5.1	0.0, 8.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	56	113	11	6	
Mean (StdDev)	5.09 (2.609)	5.00 (2.686)	2.64 (1.706)	4.35 (2.891)	
Median	5.18	4.93	2.43	4.68	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 5.7	0.0, 8.1	
C2D1 CFB					
n	56	113	11	6	
LS Mean (StdErr) [2]	-0.57 (0.168)	-0.69 (0.127)	0.36 (0.584)	-0.27 (0.851)	
95% CI [2]	-0.90, -0.24	-0.94, -0.44	-0.90, 1.62	-2.11, 1.57	
Difference (95% CI) in CFB [2]		-0.12 (-0.49, 0.24)		-0.63 (-2.06, 0.80)	
p-value [3]		0.510		0.356	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	56	111	11	6	
Mean (StdDev)	4.88 (2.644)	4.64 (2.759)	2.51 (1.946)	4.14 (3.049)	
Median	4.60	4.62	2.21	4.46	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 6.8	0.0, 7.9	
C3D1 CFB					
n	56	111	11	6	
LS Mean (StdErr) [2]	-0.73 (0.207)	-1.02 (0.157)	-0.17 (0.777)	-1.43 (1.133)	
95% CI [2]	-1.14, -0.32	-1.33, -0.71	-1.85, 1.51	-3.88, 1.02	
Difference (95% CI) in CFB [2]		-0.29 (-0.74, 0.16)		-1.26 (-3.16, 0.64)	
p-value [3]		0.203		0.176	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	54	111	10	6	
Mean (StdDev)	4.64 (2.726)	4.45 (2.866)	2.43 (2.136)	3.67 (2.936)	
Median	4.55	4.25	2.25	3.93	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 6.9	0.0, 7.1	
C4D1 CFB					
n	54	111	10	6	
LS Mean (StdErr) [2]	-0.95 (0.258)	-1.19 (0.192)	0.04 (1.051)	-1.28 (1.520)	
95% CI [2]	-1.46, -0.44	-1.57, -0.82	-2.25, 2.33	-4.59, 2.03	
Difference (95% CI) in CFB [2]		-0.24 (-0.80, 0.31)		-1.32 (-3.90, 1.27)	
p-value [3]		0.385		0.289	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	54	113	9	6	
Mean (StdDev)	4.40 (2.818)	4.43 (2.886)	2.17 (1.484)	3.19 (2.735)	
Median	4.11	4.57	2.15	3.11	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 4.3	0.0, 6.2	
C5D1 CFB					
n	54	113	9	6	
LS Mean (StdErr) [2]	-1.10 (0.285)	-1.12 (0.208)	-0.03 (0.852)	-1.93 (1.219)	
95% CI [2]	-1.66, -0.54	-1.53, -0.71	-1.90, 1.85	-4.62, 0.75	
Difference (95% CI) in CFB [2]		-0.02 (-0.64, 0.59)		-1.90 (-4.01, 0.20)	
p-value [3]		0.941		0.071	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	52	112	10	6	
Mean (StdDev)	4.44 (2.722)	4.23 (2.934)	2.78 (2.329)	3.38 (3.212)	
Median	3.96	4.11	2.54	3.32	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 7.9	0.0, 7.7	
C6D1 CFB					
n	52	112	10	6	
LS Mean (StdErr) [2]	-0.95 (0.277)	-1.28 (0.200)	0.21 (1.001)	-1.98 (1.447)	
95% CI [2]	-1.50, -0.40	-1.68, -0.89	-1.98, 2.39	-5.13, 1.18	
Difference (95% CI) in CFB [2]		-0.33 (-0.93, 0.27)		-2.18 (-4.64, 0.28)	
p-value [3]		0.275		0.077	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	52	109	10	6	
Mean (StdDev)	4.41 (2.860)	4.17 (2.978)	3.03 (2.471)	3.21 (2.977)	
Median	3.82	4.43	2.57	2.86	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 7.9	0.0, 7.1	
C7D1 CFB					
n	52	109	10	6	
LS Mean (StdErr) [2]	-1.02 (0.293)	-1.34 (0.213)	0.31 (0.888)	-2.42 (1.283)	
95% CI [2]	-1.60, -0.44	-1.76, -0.92	-1.63, 2.24	-5.21, 0.38	
Difference (95% CI) in CFB [2]		-0.32 (-0.95, 0.31)		-2.72 (-4.91, -0.54)	
Hedges'G (95% CI) in CFB		-0.15 (-0.48, 0.18)		-0.88 (-2.20, 0.14)	
p-value [3]		0.315		0.019	
					0.118

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	56	117	11	6	
Mean (StdDev)	4.67 (2.644)	4.38 (2.500)	2.14 (2.004)	3.28 (1.766)	
Median	5.00	4.07	2.14	3.60	
Min, Max	0.3, 9.9	0.0, 9.9	0.0, 6.1	0.7, 5.4	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	56	113	11	6	
Mean (StdDev)	4.30 (2.569)	3.77 (2.433)	1.99 (1.737)	2.83 (2.071)	
Median	4.29	3.57	1.79	3.02	
Min, Max	0.0, 9.1	0.0, 10.0	0.0, 5.5	0.0, 5.7	
C2D1 CFB					
n	56	113	11	6	
LS Mean (StdErr) [2]	-0.33 (0.183)	-0.60 (0.138)	-0.22 (0.799)	-1.09 (1.165)	
95% CI [2]	-0.69, 0.04	-0.87, -0.32	-1.95, 1.51	-3.60, 1.43	
Difference (95% CI) in CFB [2]		-0.27 (-0.67, 0.13)		-0.87 (-2.82, 1.09)	
p-value [3]		0.181		0.356	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	56	111	11	6	
Mean (StdDev)	3.88 (2.531)	3.41 (2.381)	1.93 (2.170)	2.32 (2.545)	
Median	3.76	2.86	1.43	1.89	
Min, Max	0.0, 9.1	0.0, 10.0	0.0, 6.6	0.0, 6.8	
C3D1 CFB					
n	56	111	11	6	
LS Mean (StdErr) [2]	-0.64 (0.237)	-0.86 (0.179)	-0.71 (0.930)	-2.47 (1.356)	
95% CI [2]	-1.11, -0.17	-1.21, -0.50	-2.72, 1.30	-5.40, 0.46	
Difference (95% CI) in CFB [2]		-0.21 (-0.73, 0.30)		-1.76 (-4.04, 0.52)	
p-value [3]		0.419		0.119	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	54	111	10	6	
Mean (StdDev)	3.91 (2.438)	3.27 (2.354)	2.09 (2.134)	2.26 (2.384)	
Median	3.69	2.83	1.61	1.79	
Min, Max	0.0, 8.4	0.0, 9.9	0.0, 6.4	0.1, 5.9	
C4D1 CFB					
n	54	111	10	6	
LS Mean (StdErr) [2]	-0.69 (0.270)	-1.04 (0.201)	-0.60 (0.915)	-2.39 (1.323)	
95% CI [2]	-1.22, -0.15	-1.44, -0.65	-2.59, 1.40	-5.28, 0.49	
Difference (95% CI) in CFB [2]		-0.36 (-0.94, 0.22)		-1.80 (-4.04, 0.45)	
p-value [3]		0.226		0.107	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	54	113	9	6	
Mean (StdDev)	3.79 (2.478)	3.22 (2.336)	2.21 (2.104)	0.85 (1.036)	
Median	3.65	2.85	2.07	0.43	
Min, Max	0.0, 9.1	0.0, 10.0	0.0, 6.6	0.0, 2.5	
C5D1 CFB					
n	54	113	9	6	
LS Mean (StdErr) [2]	-0.87 (0.270)	-1.17 (0.197)	-0.62 (0.751)	-3.58 (1.074)	
95% CI [2]	-1.41, -0.34	-1.56, -0.78	-2.27, 1.04	-5.95, -1.22	
Difference (95% CI) in CFB [2]		-0.29 (-0.87, 0.29)		-2.97 (-4.82, -1.12)	
p-value [3]		0.323		0.005	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	52	112	10	6	
Mean (StdDev)	3.55 (2.472)	2.94 (2.437)	1.90 (2.074)	0.90 (1.042)	
Median	2.95	2.46	1.25	0.57	
Min, Max	0.0, 8.9	0.0, 10.0	0.0, 6.2	0.0, 2.1	
C6D1 CFB					
n	52	112	10	6	
LS Mean (StdErr) [2]	-1.05 (0.287)	-1.42 (0.207)	-0.52 (0.563)	-3.17 (0.815)	
95% CI [2]	-1.61, -0.48	-1.83, -1.01	-1.75, 0.71	-4.95, -1.40	
Difference (95% CI) in CFB [2]		-0.37 (-0.99, 0.25)		-2.65 (-4.04, -1.27)	
p-value [3]		0.238		0.001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	52	109	10	6	
Mean (StdDev)	3.57 (2.620)	2.90 (2.399)	2.09 (2.300)	1.08 (1.379)	
Median	3.26	2.50	1.61	0.43	
Min, Max	0.0, 8.9	0.0, 10.0	0.0, 6.7	0.0, 2.9	
C7D1 CFB					
n	52	109	10	6	
LS Mean (StdErr) [2]	-1.01 (0.280)	-1.41 (0.204)	-0.93 (0.654)	-4.01 (0.945)	
95% CI [2]	-1.57, -0.46	-1.81, -1.00	-2.35, 0.49	-6.07, -1.95	
Difference (95% CI) in CFB [2]		-0.39 (-1.00, 0.21)		-3.08 (-4.69, -1.47)	
Hedges'G (95% CI) in CFB		-0.19 (-0.52, 0.15)		-1.35 (-2.82, -0.33)	
p-value [3]		0.204		0.001	
					0.118

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	56	117	11	6	
Mean (StdDev)	1.72 (1.559)	1.54 (1.743)	0.63 (0.627)	1.27 (0.768)	
Median	1.36	1.00	0.43	1.00	
Min, Max	0.0, 7.2	0.0, 12.2	0.0, 1.8	0.5, 2.7	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	56	113	11	6	
Mean (StdDev)	1.41 (1.326)	1.18 (1.504)	0.58 (0.825)	0.97 (0.681)	
Median	1.00	0.75	0.36	0.89	
Min, Max	0.0, 4.9	0.0, 10.7	0.0, 2.8	0.0, 1.9	
C2D1 CFB					
n	56	113	11	6	
LS Mean (StdErr) [2]	-0.39 (0.133)	-0.45 (0.100)	-0.26 (0.293)	-0.55 (0.427)	
95% CI [2]	-0.65, -0.12	-0.65, -0.26	-0.89, 0.37	-1.47, 0.37	
Difference (95% CI) in CFB [2]		-0.07 (-0.36, 0.22)		-0.29 (-1.01, 0.42)	
p-value [3]		0.642		0.393	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	56	111	11	6	
Mean (StdDev)	1.30 (1.217)	1.07 (1.242)	0.58 (0.685)	0.52 (0.506)	
Median	0.96	0.79	0.36	0.39	
Min, Max	0.0, 4.4	0.0, 5.8	0.0, 2.2	0.0, 1.1	
C3D1 CFB					
n	56	111	11	6	
LS Mean (StdErr) [2]	-0.50 (0.175)	-0.58 (0.132)	-0.08 (0.291)	-0.75 (0.424)	
95% CI [2]	-0.85, -0.16	-0.84, -0.32	-0.71, 0.55	-1.67, 0.16	
Difference (95% CI) in CFB [2]		-0.07 (-0.45, 0.31)		-0.67 (-1.38, 0.04)	
p-value [3]		0.703		0.064	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	54	111	10	6	
Mean (StdDev)	1.30 (1.172)	1.08 (1.452)	0.52 (0.719)	0.37 (0.400)	
Median	0.89	0.57	0.36	0.26	
Min, Max	0.0, 4.8	0.0, 9.0	0.0, 2.3	0.0, 0.9	
C4D1 CFB					
n	54	111	10	6	
LS Mean (StdErr) [2]	-0.50 (0.169)	-0.53 (0.125)	-0.29 (0.294)	-1.04 (0.426)	
95% CI [2]	-0.83, -0.17	-0.78, -0.28	-0.93, 0.35	-1.97, -0.12	
Difference (95% CI) in CFB [2]		-0.03 (-0.39, 0.33)		-0.75 (-1.48, -0.03)	
p-value [3]		0.876		0.043	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	54	113	9	6	
Mean (StdDev)	1.25 (1.208)	1.07 (1.526)	0.61 (1.027)	0.33 (0.362)	
Median	0.86	0.50	0.21	0.25	
Min, Max	0.0, 4.8	0.0, 9.6	0.0, 3.1	0.0, 0.8	
C5D1 CFB					
n	54	113	9	6	
LS Mean (StdErr) [2]	-0.60 (0.187)	-0.60 (0.136)	-0.16 (0.542)	-1.05 (0.776)	
95% CI [2]	-0.97, -0.23	-0.87, -0.33	-1.36, 1.03	-2.76, 0.65	
Difference (95% CI) in CFB [2]		0.00 (-0.40, 0.40)		-0.89 (-2.23, 0.45)	
p-value [3]		>0.999		0.172	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	52	112	10	6	
Mean (StdDev)	1.24 (1.357)	1.01 (1.343)	0.34 (0.403)	0.30 (0.291)	
Median	0.70	0.50	0.18	0.32	
Min, Max	0.0, 6.5	0.0, 9.0	0.0, 1.2	0.0, 0.8	
C6D1 CFB					
n	52	112	10	6	
LS Mean (StdErr) [2]	-0.50 (0.163)	-0.59 (0.117)	-0.36 (0.397)	-1.04 (0.573)	
95% CI [2]	-0.82, -0.17	-0.83, -0.36	-1.22, 0.51	-2.29, 0.21	
Difference (95% CI) in CFB [2]		-0.10 (-0.45, 0.25)		-0.68 (-1.66, 0.29)	
p-value [3]		0.583		0.153	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	52	109	10	6	
Mean (StdDev)	1.20 (1.329)	0.90 (1.131)	0.46 (0.537)	0.29 (0.213)	
Median	0.88	0.33	0.32	0.27	
Min, Max	0.0, 5.9	0.0, 4.8	0.0, 1.9	0.0, 0.6	
C7D1 CFB					
n	52	109	10	6	
LS Mean (StdErr) [2]	-0.51 (0.179)	-0.61 (0.130)	-0.29 (0.355)	-1.11 (0.514)	
95% CI [2]	-0.86, -0.16	-0.87, -0.36	-1.06, 0.48	-2.23, 0.00	
Difference (95% CI) in CFB [2]		-0.10 (-0.49, 0.28)		-0.83 (-1.70, 0.05)	
Hedges'G (95% CI) in CFB		-0.08 (-0.41, 0.25)		-0.67 (-1.92, 0.36)	
p-value [3]		0.595		0.062	
					0.361

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	56	117	11	6	
Mean (StdDev)	3.58 (2.651)	3.08 (2.444)	1.18 (1.306)	2.52 (2.043)	
Median	3.52	2.62	1.15	2.06	
Min, Max	0.0, 9.5	0.0, 9.5	0.0, 4.4	0.5, 6.2	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	56	113	11	6	
Mean (StdDev)	2.79 (2.492)	2.40 (2.397)	0.82 (0.831)	2.13 (1.730)	
Median	2.36	1.50	0.50	1.79	
Min, Max	0.0, 9.1	0.0, 8.9	0.0, 2.3	0.0, 5.0	
C2D1 CFB					
n	56	113	11	6	
LS Mean (StdErr) [2]	-0.67 (0.218)	-0.61 (0.165)	-1.33 (0.337)	-1.48 (0.491)	
95% CI [2]	-1.10, -0.24	-0.93, -0.28	-2.06, -0.60	-2.54, -0.42	
Difference (95% CI) in CFB [2]		0.07 (-0.41, 0.54)		-0.15 (-0.98, 0.68)	
p-value [3]		0.785		0.701	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	56	111	11	6	
Mean (StdDev)	2.60 (2.381)	2.23 (2.266)	1.02 (1.151)	1.08 (1.160)	
Median	1.58	1.57	0.50	0.61	
Min, Max	0.0, 8.7	0.0, 9.5	0.0, 2.9	0.0, 2.7	
C3D1 CFB					
n	56	111	11	6	
LS Mean (StdErr) [2]	-0.84 (0.267)	-0.75 (0.202)	-0.68 (0.657)	-1.91 (0.958)	
95% CI [2]	-1.36, -0.31	-1.15, -0.35	-2.10, 0.74	-3.98, 0.16	
Difference (95% CI) in CFB [2]		0.08 (-0.50, 0.66)		-1.23 (-2.84, 0.39)	
p-value [3]		0.776		0.124	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	54	111	10	6	
Mean (StdDev)	2.84 (2.408)	2.16 (2.351)	0.90 (1.139)	0.95 (1.011)	
Median	2.39	1.36	0.45	0.66	
Min, Max	0.0, 8.3	0.0, 8.9	0.0, 2.9	0.0, 2.3	
C4D1 CFB					
n	54	111	10	6	
LS Mean (StdErr) [2]	-0.68 (0.265)	-0.84 (0.197)	-0.94 (0.601)	-2.02 (0.869)	
95% CI [2]	-1.20, -0.15	-1.23, -0.45	-2.25, 0.37	-3.91, -0.13	
Difference (95% CI) in CFB [2]		-0.16 (-0.73, 0.41)		-1.08 (-2.56, 0.39)	
p-value [3]		0.571		0.136	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	54	113	9	6	
Mean (StdDev)	2.71 (2.442)	2.08 (2.281)	1.00 (1.273)	0.55 (0.571)	
Median	2.01	1.29	0.38	0.51	
Min, Max	0.0, 8.5	0.0, 9.0	0.0, 3.1	0.0, 1.3	
C5D1 CFB					
n	54	113	9	6	
LS Mean (StdErr) [2]	-0.85 (0.292)	-0.98 (0.213)	-1.20 (0.793)	-2.83 (1.134)	
95% CI [2]	-1.43, -0.28	-1.40, -0.56	-2.95, 0.54	-5.32, -0.33	
Difference (95% CI) in CFB [2]		-0.12 (-0.75, 0.50)		-1.62 (-3.58, 0.33)	
p-value [3]		0.698		0.095	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	52	112	10	6	
Mean (StdDev)	2.59 (2.447)	2.00 (2.265)	0.75 (1.009)	0.57 (0.525)	
Median	1.92	1.21	0.23	0.61	
Min, Max	0.0, 8.6	0.0, 8.9	0.0, 2.8	0.0, 1.4	
C6D1 CFB					
n	52	112	10	6	
LS Mean (StdErr) [2]	-0.76 (0.282)	-0.97 (0.204)	-0.83 (0.661)	-2.17 (0.956)	
95% CI [2]	-1.32, -0.21	-1.37, -0.57	-2.27, 0.62	-4.25, -0.09	
Difference (95% CI) in CFB [2]		-0.21 (-0.82, 0.40)		-1.34 (-2.97, 0.28)	
p-value [3]		0.500		0.097	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.1a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	52	109	10	6	
Mean (StdDev)	2.52 (2.584)	1.93 (2.299)	0.94 (1.168)	0.61 (0.521)	
Median	1.44	0.79	0.48	0.50	
Min, Max	0.0, 8.6	0.0, 8.7	0.0, 3.2	0.0, 1.4	
C7D1 CFB					
n	52	109	10	6	
LS Mean (StdErr) [2]	-0.86 (0.308)	-1.02 (0.224)	-0.80 (0.626)	-2.45 (0.906)	
95% CI [2]	-1.47, -0.25	-1.46, -0.58	-2.16, 0.57	-4.43, -0.48	
Difference (95% CI) in CFB [2]		-0.16 (-0.82, 0.51)		-1.66 (-3.20, -0.12)	
Hedges'G (95% CI) in CFB		-0.07 (-0.40, 0.26)		-0.76 (-2.04, 0.26)	
p-value [3]		0.641		0.037	
					0.253

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	15	35	52	88	
Mean (StdDev)	5.28 (2.654)	5.07 (2.393)	5.62 (2.368)	5.83 (2.384)	
Median	5.09	4.57	5.89	6.14	
Min, Max	0.0, 10.0	0.7, 10.0	0.0, 9.4	0.0, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	15	34	52	85	
Mean (StdDev)	4.36 (2.575)	4.71 (2.471)	5.11 (2.581)	4.91 (2.623)	
Median	4.29	3.93	5.68	5.43	
Min, Max	0.0, 10.0	0.2, 9.3	0.0, 9.0	0.0, 10.0	
C2D1 CFB					
n	15	34	52	85	
LS Mean (StdErr) [2]	-1.11 (0.254)	-0.50 (0.173)	-0.36 (0.212)	-0.76 (0.184)	
95% CI [2]	-1.62, -0.60	-0.85, -0.15	-0.78, 0.06	-1.12, -0.40	
Difference (95% CI) in CFB [2]		0.61 (0.04, 1.18)		-0.40 (-0.87, 0.06)	
p-value [3]		0.038		0.087	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	34	52	83	
Mean (StdDev)	4.41 (2.868)	4.50 (2.435)	4.96 (2.600)	4.54 (2.787)	
Median	4.29	3.70	5.44	4.50	
Min, Max	0.0, 10.0	0.8, 10.0	0.0, 9.1	0.0, 10.0	
C3D1 CFB					
n	15	34	52	83	
LS Mean (StdErr) [2]	-1.05 (0.320)	-0.69 (0.218)	-0.59 (0.249)	-1.21 (0.217)	
95% CI [2]	-1.69, -0.40	-1.13, -0.25	-1.08, -0.09	-1.64, -0.78	
Difference (95% CI) in CFB [2]		0.35 (-0.37, 1.07)		-0.62 (-1.17, -0.07)	
p-value [3]		0.328		0.026	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	15	34	49	83	
Mean (StdDev)	4.29 (3.037)	4.44 (2.565)	5.03 (2.649)	4.55 (2.894)	
Median	4.07	3.57	5.75	4.27	
Min, Max	0.0, 9.8	0.9, 9.8	0.0, 9.4	0.0, 10.0	
C4D1 CFB					
n	15	34	49	83	
LS Mean (StdErr) [2]	-1.05 (0.412)	-0.67 (0.281)	-0.51 (0.306)	-1.11 (0.259)	
95% CI [2]	-1.88, -0.22	-1.24, -0.11	-1.12, 0.09	-1.63, -0.60	
Difference (95% CI) in CFB [2]		0.38 (-0.55, 1.31)		-0.60 (-1.26, 0.06)	
p-value [3]		0.412		0.072	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	34	48	85	
Mean (StdDev)	4.31 (3.017)	4.21 (2.314)	5.02 (2.646)	4.27 (2.995)	
Median	3.36	4.18	5.57	4.50	
Min, Max	0.0, 9.8	0.0, 8.9	0.0, 9.3	0.0, 10.0	
C5D1 CFB					
n	15	34	48	85	
LS Mean (StdErr) [2]	-0.86 (0.424)	-0.76 (0.289)	-0.53 (0.329)	-1.35 (0.269)	
95% CI [2]	-1.72, -0.01	-1.34, -0.18	-1.18, 0.12	-1.88, -0.82	
Difference (95% CI) in CFB [2]		0.10 (-0.85, 1.06)		-0.81 (-1.52, -0.11)	
p-value [3]		0.831		0.024	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	15	34	47	84	
Mean (StdDev)	4.54 (3.032)	4.05 (2.191)	4.89 (2.628)	4.12 (2.947)	
Median	5.00	3.71	5.46	4.11	
Min, Max	0.0, 9.1	0.6, 9.1	0.0, 9.6	0.0, 10.0	
C6D1 CFB					
n	15	34	47	84	
LS Mean (StdErr) [2]	-0.59 (0.470)	-0.95 (0.320)	-0.47 (0.328)	-1.41 (0.269)	
95% CI [2]	-1.54, 0.35	-1.60, -0.31	-1.12, 0.18	-1.94, -0.88	
Difference (95% CI) in CFB [2]		-0.36 (-1.42, 0.70)		-0.94 (-1.65, -0.22)	
p-value [3]		0.497		0.010	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	15	34	47	81	
Mean (StdDev)	4.18 (2.775)	4.04 (2.233)	4.93 (2.700)	4.01 (3.031)	
Median	3.29	3.50	5.43	3.64	
Min, Max	0.0, 9.0	0.4, 9.0	0.0, 9.4	0.0, 10.0	
C7D1 CFB					
n	15	34	47	81	
LS Mean (StdErr) [2]	-0.95 (0.464)	-0.89 (0.317)	-0.51 (0.346)	-1.49 (0.285)	
95% CI [2]	-1.88, -0.01	-1.53, -0.26	-1.19, 0.17	-2.05, -0.92	
Difference (95% CI) in CFB [2]		0.05 (-0.99, 1.10)		-0.98 (-1.72, -0.23)	
Hedges'G (95% CI) in CFB		0.03 (-0.59, 0.65)		-0.39 (-0.76, -0.03)	
p-value [3]		0.917		0.011	
					0.146

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	15	35	52	88	
Mean (StdDev)	5.02 (2.576)	3.81 (2.022)	3.93 (2.334)	4.30 (2.244)	
Median	6.43	3.75	3.86	4.14	
Min, Max	0.0, 8.7	0.2, 9.8	0.0, 9.6	0.0, 9.6	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	15	34	52	85	
Mean (StdDev)	3.80 (1.836)	2.97 (1.926)	3.26 (2.279)	3.53 (2.235)	
Median	3.71	2.77	3.18	3.29	
Min, Max	0.0, 7.0	0.0, 7.1	0.0, 8.9	0.0, 9.4	
C2D1 CFB					
n	15	34	52	85	
LS Mean (StdErr) [2]	-1.20 (0.374)	-0.76 (0.255)	-0.59 (0.173)	-0.72 (0.150)	
95% CI [2]	-1.95, -0.45	-1.27, -0.24	-0.93, -0.25	-1.02, -0.42	
Difference (95% CI) in CFB [2]		0.44 (-0.40, 1.28)		-0.13 (-0.50, 0.25)	
p-value [3]		0.297		0.505	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	34	52	83	
Mean (StdDev)	3.18 (2.177)	2.86 (1.800)	3.18 (2.263)	2.97 (2.327)	
Median	3.00	3.04	2.96	2.43	
Min, Max	0.0, 7.6	0.0, 7.6	0.0, 8.4	0.0, 8.3	
C3D1 CFB					
n	15	34	52	83	
LS Mean (StdErr) [2]	-1.80 (0.418)	-0.85 (0.285)	-0.65 (0.226)	-1.20 (0.197)	
95% CI [2]	-2.64, -0.96	-1.42, -0.27	-1.09, -0.20	-1.59, -0.81	
Difference (95% CI) in CFB [2]		0.95 (0.01, 1.90)		-0.56 (-1.05, -0.06)	
p-value [3]		0.048		0.028	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	15	34	49	83	
Mean (StdDev)	3.07 (2.280)	2.52 (1.923)	3.18 (2.170)	2.74 (2.310)	
Median	3.23	2.35	3.29	2.36	
Min, Max	0.0, 7.4	0.0, 7.1	0.0, 7.9	0.0, 9.1	
C4D1 CFB					
n	15	34	49	83	
LS Mean (StdErr) [2]	-1.84 (0.512)	-1.14 (0.349)	-0.74 (0.273)	-1.48 (0.232)	
95% CI [2]	-2.87, -0.81	-1.84, -0.44	-1.28, -0.20	-1.94, -1.02	
Difference (95% CI) in CFB [2]		0.70 (-0.45, 1.86)		-0.74 (-1.33, -0.16)	
p-value [3]		0.225		0.013	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	34	48	85	
Mean (StdDev)	2.98 (2.196)	2.37 (1.759)	3.33 (2.213)	2.66 (2.473)	
Median	2.58	2.04	3.04	2.00	
Min, Max	0.0, 6.9	0.0, 6.9	0.0, 8.1	0.0, 9.4	
C5D1 CFB					
n	15	34	48	85	
LS Mean (StdErr) [2]	-1.84 (0.478)	-1.22 (0.326)	-0.59 (0.320)	-1.51 (0.261)	
95% CI [2]	-2.80, -0.88	-1.87, -0.56	-1.22, 0.04	-2.03, -0.99	
Difference (95% CI) in CFB [2]		0.62 (-0.45, 1.70)		-0.92 (-1.61, -0.24)	
p-value [3]		0.250		0.009	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	15	34	47	84	
Mean (StdDev)	2.64 (2.067)	2.30 (1.789)	2.73 (2.125)	2.48 (2.446)	
Median	2.86	2.18	2.29	1.82	
Min, Max	0.0, 6.9	0.0, 7.3	0.0, 7.1	0.0, 9.6	
C6D1 CFB					
n	15	34	47	84	
LS Mean (StdErr) [2]	-2.21 (0.544)	-1.37 (0.370)	-0.93 (0.313)	-1.58 (0.257)	
95% CI [2]	-3.30, -1.11	-2.12, -0.63	-1.55, -0.31	-2.09, -1.07	
Difference (95% CI) in CFB [2]		0.84 (-0.39, 2.06)		-0.65 (-1.33, 0.03)	
p-value [3]		0.177		0.060	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	15	34	47	81	
Mean (StdDev)	2.85 (2.259)	2.38 (1.813)	2.91 (2.349)	2.49 (2.388)	
Median	2.46	2.33	2.71	1.92	
Min, Max	0.0, 7.6	0.0, 7.2	0.0, 8.3	0.0, 9.4	
C7D1 CFB					
n	15	34	47	81	
LS Mean (StdErr) [2]	-2.00 (0.542)	-1.22 (0.370)	-0.88 (0.306)	-1.65 (0.252)	
95% CI [2]	-3.09, -0.91	-1.97, -0.48	-1.49, -0.28	-2.15, -1.15	
Difference (95% CI) in CFB [2]		0.78 (-0.44, 2.00)		-0.77 (-1.43, -0.11)	
Hedges'G (95% CI) in CFB		0.36 (-0.25, 1.00)		-0.35 (-0.72, 0.01)	
p-value [3]		0.207		0.023	
					0.020

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	15	35	52	88	
Mean (StdDev)	3.93 (2.628)	3.09 (2.194)	3.42 (2.434)	3.26 (2.650)	
Median	3.91	2.83	2.89	2.82	
Min, Max	0.0, 7.6	0.0, 8.5	0.0, 8.9	0.0, 9.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	15	34	52	85	
Mean (StdDev)	3.59 (2.032)	2.67 (2.123)	2.82 (2.437)	2.75 (2.458)	
Median	4.00	2.14	2.21	2.36	
Min, Max	0.0, 6.6	0.0, 7.1	0.0, 8.3	0.0, 8.8	
C2D1 CFB					
n	15	34	52	85	
LS Mean (StdErr) [2]	-0.41 (0.367)	-0.42 (0.251)	-0.46 (0.197)	-0.36 (0.171)	
95% CI [2]	-1.15, 0.33	-0.93, 0.08	-0.85, -0.07	-0.70, -0.02	
Difference (95% CI) in CFB [2]		-0.01 (-0.84, 0.82)		0.10 (-0.33, 0.53)	
p-value [3]		0.981		0.641	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	34	52	83	
Mean (StdDev)	2.86 (2.317)	2.70 (1.844)	2.59 (2.318)	2.31 (2.442)	
Median	2.77	2.56	2.00	1.36	
Min, Max	0.0, 7.6	0.0, 7.4	0.0, 7.7	0.0, 8.9	
C3D1 CFB					
n	15	34	52	83	
LS Mean (StdErr) [2]	-1.04 (0.392)	-0.30 (0.268)	-0.83 (0.244)	-0.92 (0.212)	
95% CI [2]	-1.83, -0.24	-0.84, 0.24	-1.31, -0.35	-1.34, -0.50	
Difference (95% CI) in CFB [2]		0.73 (-0.15, 1.62)		-0.09 (-0.62, 0.44)	
p-value [3]		0.102		0.741	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	15	34	49	83	
Mean (StdDev)	2.77 (2.312)	2.35 (1.980)	2.73 (2.228)	2.07 (2.355)	
Median	3.00	1.81	2.00	1.18	
Min, Max	0.0, 7.4	0.0, 8.0	0.0, 7.3	0.0, 9.2	
C4D1 CFB					
n	15	34	49	83	
LS Mean (StdErr) [2]	-1.16 (0.461)	-0.68 (0.314)	-0.80 (0.283)	-1.18 (0.240)	
95% CI [2]	-2.09, -0.23	-1.32, -0.05	-1.36, -0.24	-1.65, -0.70	
Difference (95% CI) in CFB [2]		0.48 (-0.56, 1.52)		-0.37 (-0.98, 0.23)	
p-value [3]		0.359		0.226	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	34	48	85	
Mean (StdDev)	2.90 (2.130)	2.09 (1.668)	2.76 (2.255)	2.14 (2.453)	
Median	3.25	1.88	2.55	1.23	
Min, Max	0.0, 6.9	0.0, 7.1	0.0, 8.5	0.0, 8.9	
C5D1 CFB					
n	15	34	48	85	
LS Mean (StdErr) [2]	-0.95 (0.427)	-0.88 (0.291)	-0.80 (0.324)	-1.07 (0.264)	
95% CI [2]	-1.81, -0.09	-1.46, -0.29	-1.44, -0.16	-1.59, -0.55	
Difference (95% CI) in CFB [2]		0.07 (-0.89, 1.03)		-0.27 (-0.97, 0.42)	
p-value [3]		0.883		0.440	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	15	34	47	84	
Mean (StdDev)	2.65 (2.163)	1.89 (1.714)	2.39 (2.108)	1.90 (2.356)	
Median	2.43	1.61	2.21	1.17	
Min, Max	0.0, 7.3	0.0, 6.9	0.0, 7.9	0.0, 9.9	
C6D1 CFB					
n	15	34	47	84	
LS Mean (StdErr) [2]	-1.28 (0.476)	-1.18 (0.324)	-1.06 (0.313)	-1.22 (0.257)	
95% CI [2]	-2.23, -0.32	-1.83, -0.53	-1.68, -0.44	-1.73, -0.71	
Difference (95% CI) in CFB [2]		0.10 (-0.98, 1.17)		-0.16 (-0.84, 0.52)	
p-value [3]		0.858		0.647	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	15	34	47	81	
Mean (StdDev)	2.66 (2.393)	2.04 (1.683)	2.53 (2.253)	1.90 (2.369)	
Median	2.25	1.77	2.08	1.07	
Min, Max	0.0, 7.7	0.0, 7.2	0.0, 7.3	0.0, 9.5	
C7D1 CFB					
n	15	34	47	81	
LS Mean (StdErr) [2]	-1.22 (0.494)	-0.95 (0.337)	-0.93 (0.344)	-1.22 (0.283)	
95% CI [2]	-2.21, -0.22	-1.63, -0.27	-1.61, -0.25	-1.78, -0.66	
Difference (95% CI) in CFB [2]		0.27 (-0.85, 1.38)		-0.29 (-1.03, 0.46)	
Hedges'G (95% CI) in CFB		0.14 (-0.48, 0.77)		-0.11 (-0.48, 0.25)	
p-value [3]		0.629		0.448	
					0.427

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	15	35	52	88	
Mean (StdDev)	6.67 (2.721)	4.56 (3.084)	5.85 (3.097)	5.93 (2.915)	
Median	7.07	4.29	6.48	6.20	
Min, Max	1.3, 10.0	0.0, 10.0	0.0, 10.0	0.0, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	15	34	52	85	
Mean (StdDev)	5.91 (2.631)	4.15 (2.801)	5.54 (2.941)	4.84 (2.734)	
Median	6.00	4.00	5.90	5.00	
Min, Max	1.8, 10.0	0.0, 9.1	0.0, 10.0	0.0, 10.0	
C2D1 CFB					
n	15	34	52	85	
LS Mean (StdErr) [2]	-0.79 (0.289)	-0.46 (0.197)	-0.22 (0.202)	-1.01 (0.176)	
95% CI [2]	-1.37, -0.21	-0.86, -0.07	-0.62, 0.18	-1.35, -0.66	
Difference (95% CI) in CFB [2]		0.33 (-0.33, 0.98)		-0.79 (-1.23, -0.35)	
p-value [3]		0.319		<0.001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	34	52	83	
Mean (StdDev)	6.10 (2.942)	3.83 (2.672)	5.43 (2.916)	4.37 (2.576)	
Median	6.00	3.19	5.48	4.21	
Min, Max	0.0, 10.0	0.0, 9.8	0.0, 10.0	0.0, 9.3	
C3D1 CFB					
n	15	34	52	83	
LS Mean (StdErr) [2]	-0.50 (0.364)	-0.71 (0.248)	-0.20 (0.248)	-1.37 (0.216)	
95% CI [2]	-1.23, 0.23	-1.21, -0.21	-0.70, 0.29	-1.80, -0.94	
Difference (95% CI) in CFB [2]		-0.21 (-1.03, 0.61)		-1.16 (-1.71, -0.62)	
p-value [3]		0.602		<0.0001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	15	34	49	83	
Mean (StdDev)	6.11 (2.837)	3.61 (2.679)	5.31 (2.954)	4.14 (2.562)	
Median	6.21	3.15	5.36	3.93	
Min, Max	1.8, 10.0	0.0, 9.3	0.0, 10.0	0.0, 9.4	
C4D1 CFB					
n	15	34	49	83	
LS Mean (StdErr) [2]	-0.29 (0.408)	-0.77 (0.279)	-0.17 (0.263)	-1.52 (0.223)	
95% CI [2]	-1.11, 0.53	-1.33, -0.21	-0.69, 0.35	-1.97, -1.08	
Difference (95% CI) in CFB [2]		-0.48 (-1.40, 0.44)		-1.35 (-1.92, -0.79)	
p-value [3]		0.299		<0.0001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	34	48	85	
Mean (StdDev)	6.05 (2.898)	3.47 (2.592)	5.20 (2.918)	3.88 (2.569)	
Median	6.58	3.04	5.14	3.50	
Min, Max	1.9, 10.0	0.0, 9.3	0.0, 10.0	0.0, 9.9	
C5D1 CFB					
n	15	34	48	85	
LS Mean (StdErr) [2]	-0.35 (0.428)	-0.92 (0.292)	-0.31 (0.285)	-1.77 (0.233)	
95% CI [2]	-1.22, 0.51	-1.51, -0.33	-0.87, 0.26	-2.24, -1.31	
Difference (95% CI) in CFB [2]		-0.57 (-1.53, 0.40)		-1.47 (-2.08, -0.86)	
p-value [3]		0.243		<0.0001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	15	34	47	84	
Mean (StdDev)	6.12 (2.738)	3.20 (2.298)	5.27 (2.970)	3.75 (2.680)	
Median	5.77	3.00	5.00	3.35	
Min, Max	1.7, 10.0	0.0, 7.3	0.0, 10.0	0.0, 10.0	
C6D1 CFB					
n	15	34	47	84	
LS Mean (StdErr) [2]	-0.28 (0.450)	-1.17 (0.306)	-0.16 (0.348)	-1.76 (0.285)	
95% CI [2]	-1.19, 0.62	-1.79, -0.56	-0.85, 0.53	-2.33, -1.20	
Difference (95% CI) in CFB [2]		-0.89 (-1.90, 0.12)		-1.60 (-2.36, -0.85)	
p-value [3]		0.084		<0.0001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	15	34	47	81	
Mean (StdDev)	6.18 (2.868)	3.21 (2.379)	5.29 (2.840)	3.71 (2.776)	
Median	5.93	3.00	5.00	3.33	
Min, Max	1.1, 10.0	0.0, 7.0	0.0, 10.0	0.0, 10.0	
C7D1 CFB					
n	15	34	47	81	
LS Mean (StdErr) [2]	-0.26 (0.491)	-1.21 (0.335)	-0.30 (0.354)	-1.89 (0.292)	
95% CI [2]	-1.25, 0.73	-1.88, -0.53	-1.00, 0.40	-2.47, -1.31	
Difference (95% CI) in CFB [2]		-0.95 (-2.05, 0.16)		-1.59 (-2.35, -0.82)	
Hedges'G (95% CI) in CFB		-0.48 (-1.13, 0.13)		-0.62 (-1.00, -0.26)	
p-value [3]		0.093		<0.0001	
					0.373

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	15	35	52	88	
Mean (StdDev)	6.87 (2.357)	4.96 (2.597)	5.71 (2.684)	5.65 (2.697)	
Median	7.07	4.75	5.89	6.14	
Min, Max	1.8, 10.0	0.0, 10.0	0.0, 10.0	0.0, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	15	34	52	85	
Mean (StdDev)	5.59 (2.677)	4.25 (2.402)	5.20 (2.776)	4.41 (2.368)	
Median	6.36	4.04	5.59	4.57	
Min, Max	1.0, 10.0	0.0, 9.9	0.0, 9.8	0.0, 9.6	
C2D1 CFB					
n	15	34	52	85	
LS Mean (StdErr) [2]	-1.57 (0.418)	-0.98 (0.285)	-0.46 (0.253)	-1.17 (0.220)	
95% CI [2]	-2.41, -0.73	-1.56, -0.41	-0.96, 0.04	-1.61, -0.74	
Difference (95% CI) in CFB [2]		0.58 (-0.36, 1.53)		-0.71 (-1.27, -0.16)	
p-value [3]		0.218		0.012	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	34	52	83	
Mean (StdDev)	5.45 (2.964)	3.57 (2.315)	4.87 (2.686)	3.72 (2.502)	
Median	6.07	3.18	4.74	3.79	
Min, Max	0.0, 10.0	0.0, 8.2	0.0, 9.9	0.0, 9.7	
C3D1 CFB					
n	15	34	52	83	
LS Mean (StdErr) [2]	-1.46 (0.526)	-1.48 (0.359)	-0.63 (0.311)	-1.68 (0.271)	
95% CI [2]	-2.52, -0.40	-2.20, -0.76	-1.25, -0.02	-2.22, -1.14	
Difference (95% CI) in CFB [2]		-0.02 (-1.20, 1.17)		-1.04 (-1.73, -0.36)	
p-value [3]		0.979		0.003	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	15	34	49	83	
Mean (StdDev)	5.07 (2.941)	3.40 (2.442)	4.86 (2.786)	3.46 (2.597)	
Median	4.43	3.11	5.21	3.38	
Min, Max	0.0, 10.0	0.0, 9.1	0.0, 9.8	0.0, 10.0	
C4D1 CFB					
n	15	34	49	83	
LS Mean (StdErr) [2]	-1.81 (0.636)	-1.62 (0.434)	-0.75 (0.371)	-2.04 (0.315)	
95% CI [2]	-3.09, -0.53	-2.49, -0.74	-1.49, -0.02	-2.67, -1.42	
Difference (95% CI) in CFB [2]		0.19 (-1.24, 1.62)		-1.29 (-2.09, -0.49)	
p-value [3]		0.790		0.002	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	34	48	85	
Mean (StdDev)	5.44 (2.776)	3.28 (2.329)	4.89 (2.632)	3.15 (2.599)	
Median	6.00	3.00	4.78	2.93	
Min, Max	0.9, 10.0	0.0, 8.3	0.0, 10.0	0.0, 10.0	
C5D1 CFB					
n	15	34	48	85	
LS Mean (StdErr) [2]	-1.36 (0.680)	-1.68 (0.464)	-0.68 (0.380)	-2.21 (0.311)	
95% CI [2]	-2.73, 0.01	-2.61, -0.74	-1.43, 0.08	-2.82, -1.59	
Difference (95% CI) in CFB [2]		-0.32 (-1.85, 1.21)		-1.53 (-2.35, -0.72)	
p-value [3]		0.675		<0.001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	15	34	47	84	
Mean (StdDev)	5.53 (2.585)	3.21 (2.038)	4.74 (2.698)	3.07 (2.731)	
Median	5.71	2.82	4.36	2.80	
Min, Max	0.9, 10.0	0.0, 7.6	0.0, 10.0	0.0, 10.0	
C6D1 CFB					
n	15	34	47	84	
LS Mean (StdErr) [2]	-1.32 (0.641)	-1.85 (0.436)	-0.89 (0.400)	-2.39 (0.328)	
95% CI [2]	-2.61, -0.03	-2.73, -0.97	-1.68, -0.10	-3.04, -1.74	
Difference (95% CI) in CFB [2]		-0.53 (-1.98, 0.91)		-1.50 (-2.36, -0.63)	
p-value [3]		0.460		<0.001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	15	34	47	81	
Mean (StdDev)	5.55 (2.618)	3.13 (2.165)	4.89 (2.538)	3.01 (2.647)	
Median	5.86	2.82	4.85	2.75	
Min, Max	1.1, 10.0	0.0, 7.5	0.0, 10.0	0.0, 10.0	
C7D1 CFB					
n	15	34	47	81	
LS Mean (StdErr) [2]	-1.31 (0.686)	-1.86 (0.468)	-0.85 (0.418)	-2.46 (0.345)	
95% CI [2]	-2.69, 0.07	-2.81, -0.92	-1.68, -0.02	-3.15, -1.78	
Difference (95% CI) in CFB [2]		-0.56 (-2.10, 0.99)		-1.61 (-2.52, -0.71)	
Hedges'G (95% CI) in CFB		-0.20 (-0.84, 0.41)		-0.53 (-0.91, -0.17)	
p-value [3]		0.471		<0.001	
					0.240

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	15	35	52	88	
Mean (StdDev)	5.90 (2.249)	4.77 (2.522)	5.95 (2.652)	5.64 (2.331)	
Median	5.93	4.92	5.78	5.96	
Min, Max	2.6, 10.0	0.0, 10.0	0.0, 10.0	0.0, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	15	34	52	85	
Mean (StdDev)	5.35 (2.162)	4.39 (2.580)	5.40 (2.772)	4.80 (2.418)	
Median	5.73	4.07	5.01	5.07	
Min, Max	2.5, 9.2	0.0, 8.2	0.0, 10.0	0.0, 10.0	
C2D1 CFB					
n	15	34	52	85	
LS Mean (StdErr) [2]	-0.71 (0.338)	-0.54 (0.231)	-0.50 (0.246)	-0.79 (0.214)	
95% CI [2]	-1.39, -0.03	-1.01, -0.08	-0.98, -0.01	-1.21, -0.37	
Difference (95% CI) in CFB [2]		0.17 (-0.59, 0.94)		-0.29 (-0.83, 0.24)	
p-value [3]		0.651		0.281	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	34	52	83	
Mean (StdDev)	5.03 (2.519)	3.76 (2.567)	5.25 (2.891)	4.30 (2.479)	
Median	5.14	3.48	5.29	4.29	
Min, Max	0.9, 8.9	0.0, 8.8	0.0, 10.0	0.0, 10.0	
C3D1 CFB					
n	15	34	52	83	
LS Mean (StdErr) [2]	-0.91 (0.403)	-1.07 (0.275)	-0.56 (0.300)	-1.23 (0.262)	
95% CI [2]	-1.73, -0.10	-1.63, -0.52	-1.16, 0.03	-1.74, -0.71	
Difference (95% CI) in CFB [2]		-0.16 (-1.07, 0.75)		-0.66 (-1.32, -0.01)	
p-value [3]		0.724		0.048	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	15	34	49	83	
Mean (StdDev)	4.43 (2.684)	3.63 (2.657)	5.39 (2.887)	4.04 (2.476)	
Median	4.15	3.40	5.57	3.85	
Min, Max	1.2, 9.7	0.0, 8.4	0.0, 10.0	0.0, 10.0	
C4D1 CFB					
n	15	34	49	83	
LS Mean (StdErr) [2]	-1.51 (0.462)	-1.21 (0.316)	-0.54 (0.347)	-1.60 (0.294)	
95% CI [2]	-2.45, -0.58	-1.84, -0.57	-1.23, 0.14	-2.18, -1.02	
Difference (95% CI) in CFB [2]		0.30 (-0.74, 1.35)		-1.05 (-1.80, -0.31)	
p-value [3]		0.559		0.006	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	34	48	85	
Mean (StdDev)	4.66 (2.653)	3.48 (2.679)	5.37 (2.907)	3.83 (2.494)	
Median	4.29	3.26	5.52	3.92	
Min, Max	1.1, 9.9	0.0, 9.0	0.0, 10.0	0.0, 9.8	
C5D1 CFB					
n	15	34	48	85	
LS Mean (StdErr) [2]	-1.26 (0.478)	-1.34 (0.326)	-0.62 (0.391)	-1.81 (0.319)	
95% CI [2]	-2.22, -0.29	-2.00, -0.68	-1.39, 0.16	-2.45, -1.18	
Difference (95% CI) in CFB [2]		-0.08 (-1.16, 1.00)		-1.20 (-2.04, -0.36)	
p-value [3]		0.878		0.005	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	15	34	47	84	
Mean (StdDev)	4.74 (2.604)	3.47 (2.621)	5.15 (2.986)	3.65 (2.577)	
Median	5.23	3.54	5.00	3.46	
Min, Max	0.6, 9.6	0.0, 9.0	0.0, 10.0	0.0, 10.0	
C6D1 CFB					
n	15	34	47	84	
LS Mean (StdErr) [2]	-1.27 (0.496)	-1.42 (0.337)	-0.86 (0.405)	-1.99 (0.332)	
95% CI [2]	-2.27, -0.27	-2.10, -0.74	-1.66, -0.06	-2.65, -1.34	
Difference (95% CI) in CFB [2]		-0.15 (-1.27, 0.97)		-1.14 (-2.01, -0.26)	
p-value [3]		0.785		0.012	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	15	34	47	81	
Mean (StdDev)	4.83 (2.628)	3.36 (2.632)	5.21 (2.910)	3.35 (2.529)	
Median	5.14	2.86	5.36	3.23	
Min, Max	0.4, 10.0	0.0, 8.9	0.0, 10.0	0.0, 10.0	
C7D1 CFB					
n	15	34	47	81	
LS Mean (StdErr) [2]	-1.06 (0.573)	-1.43 (0.391)	-0.88 (0.413)	-2.19 (0.340)	
95% CI [2]	-2.22, 0.09	-2.22, -0.65	-1.70, -0.07	-2.87, -1.52	
Difference (95% CI) in CFB [2]		-0.37 (-1.67, 0.92)		-1.31 (-2.20, -0.42)	
Hedges'G (95% CI) in CFB		-0.16 (-0.79, 0.45)		-0.44 (-0.81, -0.08)	
p-value [3]		0.565		0.004	
					0.272

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	15	35	52	88	
Mean (StdDev)	6.92 (2.129)	6.10 (1.754)	6.75 (1.983)	7.28 (1.982)	
Median	6.54	6.54	6.75	7.61	
Min, Max	2.7, 10.0	2.4, 9.4	0.0, 10.0	0.1, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	15	34	52	85	
Mean (StdDev)	6.27 (2.188)	5.72 (1.808)	6.40 (1.875)	6.48 (2.315)	
Median	6.29	6.04	6.30	6.57	
Min, Max	3.3, 9.9	1.0, 9.1	2.3, 10.0	0.1, 10.0	
C2D1 CFB					
n	15	34	52	85	
LS Mean (StdErr) [2]	-0.70 (0.254)	-0.48 (0.173)	-0.38 (0.209)	-0.83 (0.182)	
95% CI [2]	-1.21, -0.19	-0.83, -0.13	-0.79, 0.04	-1.19, -0.47	
Difference (95% CI) in CFB [2]		0.22 (-0.36, 0.79)		-0.45 (-0.91, 0.01)	
p-value [3]		0.448		0.053	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	34	52	83	
Mean (StdDev)	5.93 (2.478)	5.37 (1.835)	6.06 (2.221)	6.00 (2.459)	
Median	5.36	5.50	6.00	6.00	
Min, Max	2.7, 9.9	1.8, 9.0	0.3, 10.0	0.2, 10.0	
C3D1 CFB					
n	15	34	52	83	
LS Mean (StdErr) [2]	-1.13 (0.354)	-0.90 (0.242)	-0.67 (0.266)	-1.24 (0.232)	
95% CI [2]	-1.84, -0.42	-1.39, -0.42	-1.20, -0.14	-1.70, -0.78	
Difference (95% CI) in CFB [2]		0.23 (-0.57, 1.03)		-0.57 (-1.15, 0.01)	
p-value [3]		0.567		0.055	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	15	34	49	83	
Mean (StdDev)	5.38 (2.914)	5.18 (1.992)	5.97 (2.214)	5.66 (2.649)	
Median	4.69	5.26	6.00	5.69	
Min, Max	0.2, 9.9	1.1, 9.1	1.3, 10.0	0.0, 10.0	
C4D1 CFB					
n	15	34	49	83	
LS Mean (StdErr) [2]	-1.58 (0.443)	-1.01 (0.302)	-0.80 (0.330)	-1.64 (0.280)	
95% CI [2]	-2.47, -0.69	-1.62, -0.40	-1.45, -0.14	-2.20, -1.09	
Difference (95% CI) in CFB [2]		0.57 (-0.43, 1.57)		-0.84 (-1.56, -0.13)	
p-value [3]		0.255		0.020	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	34	48	85	
Mean (StdDev)	5.36 (2.855)	4.94 (1.937)	5.82 (2.294)	5.68 (2.605)	
Median	5.17	5.00	5.68	5.91	
Min, Max	0.6, 9.9	1.4, 9.0	1.2, 10.0	0.0, 10.0	
C5D1 CFB					
n	15	34	48	85	
LS Mean (StdErr) [2]	-1.33 (0.474)	-1.04 (0.323)	-0.98 (0.342)	-1.61 (0.279)	
95% CI [2]	-2.28, -0.37	-1.69, -0.39	-1.65, -0.30	-2.17, -1.06	
Difference (95% CI) in CFB [2]		0.29 (-0.78, 1.36)		-0.64 (-1.37, 0.10)	
p-value [3]		0.588		0.088	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	15	34	47	84	
Mean (StdDev)	5.45 (2.653)	4.60 (2.186)	5.91 (2.314)	5.45 (2.880)	
Median	5.00	4.89	6.00	5.62	
Min, Max	1.1, 9.6	0.0, 9.4	0.4, 10.0	0.0, 10.0	
C6D1 CFB					
n	15	34	47	84	
LS Mean (StdErr) [2]	-1.34 (0.502)	-1.40 (0.342)	-0.73 (0.367)	-1.75 (0.301)	
95% CI [2]	-2.36, -0.33	-2.09, -0.72	-1.46, -0.01	-2.35, -1.16	
Difference (95% CI) in CFB [2]		-0.06 (-1.19, 1.07)		-1.02 (-1.82, -0.22)	
p-value [3]		0.915		0.012	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	15	34	47	81	
Mean (StdDev)	5.23 (2.725)	4.79 (2.023)	5.93 (2.417)	5.15 (2.855)	
Median	4.93	4.96	5.79	5.22	
Min, Max	0.4, 10.0	0.0, 9.0	0.2, 10.0	0.0, 10.0	
C7D1 CFB					
n	15	34	47	81	
LS Mean (StdErr) [2]	-1.55 (0.530)	-1.25 (0.362)	-0.74 (0.365)	-2.00 (0.301)	
95% CI [2]	-2.62, -0.49	-1.98, -0.53	-1.47, -0.02	-2.60, -1.41	
Difference (95% CI) in CFB [2]		0.30 (-0.90, 1.50)		-1.26 (-2.04, -0.47)	
Hedges'G (95% CI) in CFB		0.14 (-0.48, 0.77)		-0.47 (-0.85, -0.12)	
p-value [3]		0.616		0.002	
					0.038

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	15	35	52	88	
Mean (StdDev)	4.69 (3.170)	3.21 (2.667)	3.43 (2.618)	4.26 (2.832)	
Median	4.86	2.80	2.93	4.39	
Min, Max	0.0, 8.4	0.0, 8.9	0.0, 9.3	0.0, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	15	34	52	85	
Mean (StdDev)	4.16 (2.918)	3.12 (2.586)	2.94 (2.569)	3.47 (2.707)	
Median	3.73	2.86	2.45	3.00	
Min, Max	0.0, 8.7	0.0, 8.1	0.0, 8.4	0.0, 10.0	
C2D1 CFB					
n	15	34	52	85	
LS Mean (StdErr) [2]	-0.73 (0.313)	-0.29 (0.214)	-0.39 (0.232)	-0.71 (0.202)	
95% CI [2]	-1.36, -0.10	-0.72, 0.14	-0.85, 0.07	-1.10, -0.31	
Difference (95% CI) in CFB [2]		0.44 (-0.26, 1.15)		-0.32 (-0.82, 0.19)	
p-value [3]		0.212		0.220	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	34	52	83	
Mean (StdDev)	3.83 (2.955)	2.81 (2.363)	2.61 (2.419)	3.03 (2.838)	
Median	3.14	2.15	1.96	2.43	
Min, Max	0.0, 8.0	0.0, 8.1	0.0, 8.1	0.0, 10.0	
C3D1 CFB					
n	15	34	52	83	
LS Mean (StdErr) [2]	-1.03 (0.342)	-0.58 (0.234)	-0.68 (0.273)	-1.11 (0.238)	
95% CI [2]	-1.72, -0.34	-1.05, -0.11	-1.22, -0.14	-1.58, -0.64	
Difference (95% CI) in CFB [2]		0.45 (-0.32, 1.23)		-0.43 (-1.03, 0.17)	
p-value [3]		0.243		0.157	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	15	34	49	83	
Mean (StdDev)	3.98 (3.151)	2.88 (2.459)	2.77 (2.444)	2.90 (2.871)	
Median	3.69	2.35	2.50	2.00	
Min, Max	0.0, 9.9	0.0, 8.5	0.0, 8.1	0.0, 10.0	
C4D1 CFB					
n	15	34	49	83	
LS Mean (StdErr) [2]	-0.87 (0.408)	-0.48 (0.279)	-0.55 (0.337)	-1.27 (0.286)	
95% CI [2]	-1.69, -0.05	-1.05, 0.08	-1.21, 0.12	-1.83, -0.70	
Difference (95% CI) in CFB [2]		0.39 (-0.54, 1.31)		-0.72 (-1.44, 0.01)	
p-value [3]		0.404		0.052	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	34	48	85	
Mean (StdDev)	3.95 (3.164)	2.69 (2.403)	2.79 (2.377)	2.74 (2.774)	
Median	2.93	2.00	2.14	1.93	
Min, Max	0.0, 9.6	0.0, 8.0	0.0, 7.8	0.0, 10.0	
C5D1 CFB					
n	15	34	48	85	
LS Mean (StdErr) [2]	-0.71 (0.397)	-0.52 (0.271)	-0.51 (0.334)	-1.33 (0.273)	
95% CI [2]	-1.51, 0.09	-1.07, 0.02	-1.17, 0.15	-1.87, -0.79	
Difference (95% CI) in CFB [2]		0.18 (-0.71, 1.08)		-0.81 (-1.53, -0.10)	
p-value [3]		0.683		0.026	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	15	34	47	84	
Mean (StdDev)	3.80 (3.079)	2.44 (2.180)	2.56 (2.385)	2.46 (2.718)	
Median	3.43	2.18	1.71	1.71	
Min, Max	0.0, 8.6	0.0, 7.6	0.0, 8.3	0.0, 10.0	
C6D1 CFB					
n	15	34	47	84	
LS Mean (StdErr) [2]	-0.94 (0.440)	-0.76 (0.299)	-0.74 (0.353)	-1.59 (0.290)	
95% CI [2]	-1.83, -0.06	-1.37, -0.16	-1.44, -0.04	-2.16, -1.02	
Difference (95% CI) in CFB [2]		0.18 (-0.81, 1.17)		-0.85 (-1.62, -0.08)	
p-value [3]		0.716		0.030	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	15	34	47	81	
Mean (StdDev)	3.93 (3.194)	2.53 (2.180)	2.53 (2.405)	2.44 (2.744)	
Median	4.31	2.00	1.86	1.58	
Min, Max	0.0, 10.0	0.0, 7.5	0.0, 8.8	0.0, 10.0	
C7D1 CFB					
n	15	34	47	81	
LS Mean (StdErr) [2]	-0.86 (0.410)	-0.78 (0.280)	-0.78 (0.378)	-1.54 (0.311)	
95% CI [2]	-1.68, -0.03	-1.34, -0.22	-1.53, -0.04	-2.16, -0.92	
Difference (95% CI) in CFB [2]		0.08 (-0.85, 1.00)		-0.76 (-1.57, 0.06)	
Hedges'G (95% CI) in CFB		0.05 (-0.57, 0.67)		-0.28 (-0.65, 0.08)	
p-value [3]		0.868		0.069	
					0.280

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	15	35	52	88	
Mean (StdDev)	5.12 (3.057)	5.02 (2.047)	5.26 (2.589)	5.93 (2.537)	
Median	5.07	5.00	5.46	6.08	
Min, Max	0.0, 9.1	0.0, 10.0	0.0, 10.0	0.0, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	15	34	52	85	
Mean (StdDev)	4.42 (2.996)	4.66 (2.093)	4.77 (2.551)	5.08 (2.894)	
Median	3.64	4.61	4.46	5.29	
Min, Max	0.0, 9.5	0.0, 10.0	0.0, 10.0	0.0, 10.0	
C2D1 CFB					
n	15	34	52	85	
LS Mean (StdErr) [2]	-0.83 (0.248)	-0.53 (0.169)	-0.41 (0.189)	-0.77 (0.164)	
95% CI [2]	-1.33, -0.33	-0.87, -0.18	-0.78, -0.04	-1.09, -0.44	
Difference (95% CI) in CFB [2]		0.31 (-0.25, 0.87)		-0.36 (-0.77, 0.06)	
p-value [3]		0.277		0.091	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	34	52	83	
Mean (StdDev)	3.96 (2.963)	4.37 (2.057)	4.65 (2.603)	4.72 (3.009)	
Median	3.46	4.41	4.29	4.92	
Min, Max	0.0, 8.8	0.0, 10.0	0.0, 10.0	0.0, 10.0	
C3D1 CFB					
n	15	34	52	83	
LS Mean (StdErr) [2]	-1.31 (0.269)	-0.83 (0.184)	-0.49 (0.239)	-1.12 (0.208)	
95% CI [2]	-1.86, -0.77	-1.20, -0.46	-0.96, -0.02	-1.53, -0.71	
Difference (95% CI) in CFB [2]		0.48 (-0.13, 1.09)		-0.63 (-1.15, -0.11)	
p-value [3]		0.119		0.019	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	15	34	49	83	
Mean (StdDev)	3.91 (2.954)	4.25 (2.112)	4.41 (2.705)	4.47 (3.127)	
Median	2.86	3.99	4.29	4.50	
Min, Max	0.0, 9.9	0.0, 9.9	0.0, 10.0	0.0, 10.0	
C4D1 CFB					
n	15	34	49	83	
LS Mean (StdErr) [2]	-1.29 (0.323)	-0.89 (0.220)	-0.78 (0.308)	-1.38 (0.261)	
95% CI [2]	-1.94, -0.64	-1.34, -0.45	-1.39, -0.17	-1.89, -0.86	
Difference (95% CI) in CFB [2]		0.40 (-0.33, 1.13)		-0.60 (-1.26, 0.06)	
p-value [3]		0.272		0.076	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	34	48	85	
Mean (StdDev)	3.75 (3.136)	4.04 (2.210)	4.19 (2.677)	4.49 (3.111)	
Median	3.42	3.93	3.80	4.67	
Min, Max	0.0, 9.9	0.0, 10.0	0.0, 10.0	0.0, 10.0	
C5D1 CFB					
n	15	34	48	85	
LS Mean (StdErr) [2]	-1.31 (0.368)	-0.99 (0.251)	-0.91 (0.337)	-1.24 (0.276)	
95% CI [2]	-2.05, -0.57	-1.50, -0.49	-1.58, -0.25	-1.79, -0.69	
Difference (95% CI) in CFB [2]		0.32 (-0.51, 1.15)		-0.33 (-1.05, 0.40)	
p-value [3]		0.444		0.374	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	15	34	47	84	
Mean (StdDev)	3.95 (3.059)	4.02 (2.265)	4.24 (2.628)	4.25 (3.182)	
Median	3.07	4.00	3.92	4.46	
Min, Max	0.0, 9.6	0.0, 10.0	0.0, 10.0	0.0, 10.0	
C6D1 CFB					
n	15	34	47	84	
LS Mean (StdErr) [2]	-1.22 (0.376)	-1.06 (0.256)	-0.72 (0.327)	-1.43 (0.268)	
95% CI [2]	-1.98, -0.46	-1.57, -0.54	-1.37, -0.08	-1.96, -0.90	
Difference (95% CI) in CFB [2]		0.16 (-0.69, 1.01)		-0.70 (-1.41, 0.00)	
p-value [3]		0.701		0.051	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	15	34	47	81	
Mean (StdDev)	3.81 (2.984)	4.01 (2.271)	4.31 (2.799)	4.16 (3.234)	
Median	3.08	4.04	3.85	4.46	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 10.0	0.0, 10.0	
C7D1 CFB					
n	15	34	47	81	
LS Mean (StdErr) [2]	-1.36 (0.384)	-1.11 (0.262)	-0.70 (0.344)	-1.50 (0.284)	
95% CI [2]	-2.13, -0.59	-1.63, -0.58	-1.38, -0.02	-2.06, -0.93	
Difference (95% CI) in CFB [2]		0.25 (-0.61, 1.12)		-0.80 (-1.54, -0.05)	
Hedges'G (95% CI) in CFB		0.16 (-0.45, 0.80)		-0.32 (-0.69, 0.04)	
p-value [3]		0.560		0.036	
					0.136

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	15	35	52	88	
Mean (StdDev)	4.60 (2.701)	3.47 (2.321)	4.15 (2.725)	4.66 (2.465)	
Median	5.00	3.15	4.25	4.55	
Min, Max	0.0, 8.4	0.0, 7.9	0.3, 9.9	0.0, 9.9	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	15	34	52	85	
Mean (StdDev)	3.93 (2.373)	3.01 (2.314)	3.92 (2.669)	4.01 (2.413)	
Median	4.21	2.39	3.61	3.79	
Min, Max	0.0, 8.1	0.0, 8.1	0.1, 9.1	0.0, 10.0	
C2D1 CFB					
n	15	34	52	85	
LS Mean (StdErr) [2]	-0.79 (0.235)	-0.56 (0.160)	-0.23 (0.218)	-0.65 (0.190)	
95% CI [2]	-1.27, -0.32	-0.88, -0.23	-0.66, 0.21	-1.03, -0.28	
Difference (95% CI) in CFB [2]		0.24 (-0.29, 0.77)		-0.43 (-0.90, 0.05)	
p-value [3]		0.375		0.078	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	34	52	83	
Mean (StdDev)	3.38 (2.402)	2.82 (2.124)	3.61 (2.629)	3.58 (2.470)	
Median	3.08	2.56	3.18	3.07	
Min, Max	0.0, 8.1	0.0, 7.7	0.0, 9.1	0.0, 10.0	
C3D1 CFB					
n	15	34	52	83	
LS Mean (StdErr) [2]	-1.27 (0.436)	-0.69 (0.298)	-0.49 (0.259)	-1.03 (0.225)	
95% CI [2]	-2.14, -0.39	-1.28, -0.09	-1.00, 0.02	-1.48, -0.59	
Difference (95% CI) in CFB [2]		0.58 (-0.40, 1.56)		-0.54 (-1.11, 0.02)	
p-value [3]		0.240		0.061	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	15	34	49	83	
Mean (StdDev)	3.60 (2.358)	2.79 (2.105)	3.63 (2.525)	3.39 (2.441)	
Median	3.50	2.44	3.29	3.07	
Min, Max	0.0, 8.1	0.0, 7.7	0.0, 8.4	0.0, 9.9	
C4D1 CFB					
n	15	34	49	83	
LS Mean (StdErr) [2]	-0.98 (0.419)	-0.67 (0.286)	-0.64 (0.308)	-1.33 (0.261)	
95% CI [2]	-1.83, -0.14	-1.24, -0.09	-1.25, -0.03	-1.85, -0.81	
Difference (95% CI) in CFB [2]		0.31 (-0.63, 1.26)		-0.69 (-1.35, -0.03)	
p-value [3]		0.507		0.040	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	34	48	85	
Mean (StdDev)	3.33 (2.561)	2.52 (2.010)	3.64 (2.472)	3.33 (2.439)	
Median	2.83	2.18	3.46	3.14	
Min, Max	0.0, 9.0	0.0, 7.1	0.0, 9.1	0.0, 10.0	
C5D1 CFB					
n	15	34	48	85	
LS Mean (StdErr) [2]	-1.22 (0.382)	-0.91 (0.260)	-0.74 (0.314)	-1.44 (0.256)	
95% CI [2]	-1.98, -0.45	-1.43, -0.38	-1.36, -0.12	-1.94, -0.93	
Difference (95% CI) in CFB [2]		0.31 (-0.55, 1.17)		-0.70 (-1.37, -0.03)	
p-value [3]		0.471		0.042	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	15	34	47	84	
Mean (StdDev)	3.20 (2.366)	2.30 (1.994)	3.31 (2.531)	3.05 (2.559)	
Median	2.69	1.77	2.90	2.63	
Min, Max	0.0, 8.9	0.0, 7.1	0.0, 8.3	0.0, 10.0	
C6D1 CFB					
n	15	34	47	84	
LS Mean (StdErr) [2]	-1.51 (0.428)	-1.23 (0.291)	-0.82 (0.318)	-1.62 (0.261)	
95% CI [2]	-2.38, -0.65	-1.82, -0.64	-1.45, -0.19	-2.14, -1.11	
Difference (95% CI) in CFB [2]		0.28 (-0.68, 1.25)		-0.80 (-1.49, -0.11)	
p-value [3]		0.557		0.023	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	15	34	47	81	
Mean (StdDev)	3.18 (2.625)	2.46 (2.112)	3.38 (2.635)	2.95 (2.493)	
Median	2.86	1.89	2.86	2.69	
Min, Max	0.0, 8.9	0.0, 7.4	0.0, 7.9	0.0, 10.0	
C7D1 CFB					
n	15	34	47	81	
LS Mean (StdErr) [2]	-1.45 (0.471)	-1.03 (0.321)	-0.79 (0.306)	-1.69 (0.252)	
95% CI [2]	-2.39, -0.50	-1.68, -0.39	-1.39, -0.18	-2.19, -1.19	
Difference (95% CI) in CFB [2]		0.41 (-0.65, 1.47)		-0.90 (-1.56, -0.24)	
Hedges'G (95% CI) in CFB		0.22 (-0.40, 0.85)		-0.41 (-0.78, -0.05)	
p-value [3]		0.438		0.008	
					0.042

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	15	35	52	88	
Mean (StdDev)	1.74 (1.945)	1.62 (1.441)	1.48 (1.363)	1.49 (1.809)	
Median	1.14	1.25	1.19	0.89	
Min, Max	0.0, 7.2	0.0, 5.6	0.0, 6.1	0.0, 12.2	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	15	34	52	85	
Mean (StdDev)	1.44 (1.395)	1.33 (1.189)	1.22 (1.267)	1.10 (1.574)	
Median	1.00	1.00	0.61	0.57	
Min, Max	0.0, 3.8	0.0, 4.3	0.0, 4.9	0.0, 10.7	
C2D1 CFB					
n	15	34	52	85	
LS Mean (StdErr) [2]	-0.35 (0.255)	-0.34 (0.174)	-0.38 (0.136)	-0.52 (0.119)	
95% CI [2]	-0.86, 0.16	-0.69, 0.01	-0.65, -0.11	-0.75, -0.28	
Difference (95% CI) in CFB [2]		0.01 (-0.57, 0.58)		-0.14 (-0.44, 0.15)	
p-value [3]		0.983		0.340	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	34	52	83	
Mean (StdDev)	1.06 (1.231)	1.38 (1.469)	1.21 (1.166)	0.90 (1.082)	
Median	0.31	1.00	0.89	0.50	
Min, Max	0.0, 3.4	0.0, 5.8	0.0, 4.4	0.0, 5.6	
C3D1 CFB					
n	15	34	52	83	
LS Mean (StdErr) [2]	-0.61 (0.254)	-0.20 (0.173)	-0.48 (0.188)	-0.80 (0.164)	
95% CI [2]	-1.13, -0.10	-0.55, 0.15	-0.85, -0.11	-1.12, -0.48	
Difference (95% CI) in CFB [2]		0.42 (-0.15, 0.99)		-0.32 (-0.73, 0.09)	
p-value [3]		0.149		0.125	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	15	34	49	83	
Mean (StdDev)	1.28 (1.435)	1.12 (1.209)	1.14 (1.055)	1.01 (1.510)	
Median	0.71	0.84	0.77	0.38	
Min, Max	0.0, 4.8	0.0, 5.4	0.0, 4.3	0.0, 9.0	
C4D1 CFB					
n	15	34	49	83	
LS Mean (StdErr) [2]	-0.44 (0.253)	-0.49 (0.173)	-0.51 (0.187)	-0.59 (0.159)	
95% CI [2]	-0.95, 0.07	-0.84, -0.15	-0.88, -0.14	-0.91, -0.28	
Difference (95% CI) in CFB [2]		-0.05 (-0.62, 0.52)		-0.09 (-0.49, 0.32)	
p-value [3]		0.860		0.674	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	34	48	85	
Mean (StdDev)	1.37 (1.472)	1.01 (1.084)	1.09 (1.108)	1.04 (1.640)	
Median	0.93	0.59	0.64	0.43	
Min, Max	0.0, 4.8	0.0, 4.6	0.0, 4.0	0.0, 9.6	
C5D1 CFB					
n	15	34	48	85	
LS Mean (StdErr) [2]	-0.38 (0.287)	-0.63 (0.196)	-0.59 (0.212)	-0.62 (0.173)	
95% CI [2]	-0.96, 0.19	-1.03, -0.24	-1.01, -0.17	-0.96, -0.28	
Difference (95% CI) in CFB [2]		-0.25 (-0.90, 0.40)		-0.03 (-0.49, 0.42)	
p-value [3]		0.444		0.892	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	15	34	47	84	
Mean (StdDev)	1.50 (1.906)	0.95 (0.924)	0.96 (1.021)	0.98 (1.453)	
Median	0.50	0.53	0.67	0.45	
Min, Max	0.0, 6.5	0.0, 3.3	0.0, 4.3	0.0, 9.0	
C6D1 CFB					
n	15	34	47	84	
LS Mean (StdErr) [2]	-0.22 (0.229)	-0.57 (0.156)	-0.61 (0.184)	-0.65 (0.151)	
95% CI [2]	-0.68, 0.24	-0.88, -0.26	-0.98, -0.25	-0.95, -0.35	
Difference (95% CI) in CFB [2]		-0.35 (-0.87, 0.17)		-0.04 (-0.44, 0.36)	
p-value [3]		0.180		0.845	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	15	34	47	81	
Mean (StdDev)	1.54 (1.799)	0.95 (1.086)	0.93 (1.017)	0.84 (1.125)	
Median	0.79	0.35	0.50	0.29	
Min, Max	0.0, 5.9	0.0, 4.0	0.0, 4.1	0.0, 4.8	
C7D1 CFB					
n	15	34	47	81	
LS Mean (StdErr) [2]	-0.21 (0.269)	-0.70 (0.184)	-0.57 (0.198)	-0.60 (0.163)	
95% CI [2]	-0.76, 0.33	-1.07, -0.33	-0.96, -0.17	-0.93, -0.28	
Difference (95% CI) in CFB [2]		-0.48 (-1.09, 0.13)		-0.04 (-0.47, 0.39)	
Hedges'G (95% CI) in CFB		-0.45 (-1.10, 0.16)		-0.03 (-0.39, 0.34)	
p-value [3]		0.117		0.865	
					0.282

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	15	35	52	88	
Mean (StdDev)	3.48 (2.770)	3.40 (2.280)	3.10 (2.610)	2.92 (2.475)	
Median	4.00	3.07	2.39	2.35	
Min, Max	0.0, 7.9	0.0, 8.5	0.0, 9.5	0.0, 9.5	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	15	34	52	85	
Mean (StdDev)	2.77 (2.212)	2.93 (2.459)	2.38 (2.481)	2.17 (2.303)	
Median	2.92	2.14	1.54	1.14	
Min, Max	0.0, 6.7	0.0, 8.2	0.0, 9.1	0.0, 8.9	
C2D1 CFB					
n	15	34	52	85	
LS Mean (StdErr) [2]	-0.58 (0.407)	-0.38 (0.278)	-0.66 (0.227)	-0.72 (0.198)	
95% CI [2]	-1.40, 0.24	-0.94, 0.18	-1.11, -0.21	-1.11, -0.32	
Difference (95% CI) in CFB [2]		0.20 (-0.72, 1.12)		-0.06 (-0.55, 0.44)	
p-value [3]		0.662		0.820	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	34	52	83	
Mean (StdDev)	2.21 (2.217)	2.94 (2.550)	2.38 (2.338)	1.85 (2.023)	
Median	1.50	2.52	1.58	1.14	
Min, Max	0.0, 6.9	0.0, 9.5	0.0, 8.7	0.0, 8.1	
C3D1 CFB					
n	15	34	52	83	
LS Mean (StdErr) [2]	-0.93 (0.507)	-0.19 (0.346)	-0.75 (0.270)	-1.07 (0.236)	
95% CI [2]	-1.95, 0.09	-0.89, 0.50	-1.28, -0.21	-1.54, -0.61	
Difference (95% CI) in CFB [2]		0.74 (-0.40, 1.88)		-0.33 (-0.92, 0.27)	
p-value [3]		0.200		0.278	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	15	34	49	83	
Mean (StdDev)	2.58 (2.372)	2.50 (2.260)	2.52 (2.381)	1.93 (2.329)	
Median	2.21	2.25	2.07	1.00	
Min, Max	0.0, 6.6	0.0, 7.5	0.0, 8.3	0.0, 8.9	
C4D1 CFB					
n	15	34	49	83	
LS Mean (StdErr) [2]	-0.67 (0.452)	-0.73 (0.308)	-0.60 (0.286)	-0.91 (0.242)	
95% CI [2]	-1.58, 0.24	-1.35, -0.11	-1.17, -0.04	-1.39, -0.43	
Difference (95% CI) in CFB [2]		-0.06 (-1.08, 0.96)		-0.31 (-0.92, 0.31)	
p-value [3]		0.902		0.324	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	34	48	85	
Mean (StdDev)	2.77 (2.283)	2.26 (2.195)	2.37 (2.427)	1.90 (2.277)	
Median	2.23	1.52	1.07	1.00	
Min, Max	0.0, 7.3	0.0, 7.9	0.0, 8.5	0.0, 9.0	
C5D1 CFB					
n	15	34	48	85	
LS Mean (StdErr) [2]	-0.49 (0.515)	-0.97 (0.352)	-0.85 (0.319)	-1.03 (0.261)	
95% CI [2]	-1.52, 0.55	-1.68, -0.26	-1.49, -0.22	-1.55, -0.52	
Difference (95% CI) in CFB [2]		-0.48 (-1.65, 0.68)		-0.18 (-0.86, 0.51)	
p-value [3]		0.406		0.608	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	15	34	47	84	
Mean (StdDev)	2.60 (2.449)	2.30 (2.375)	2.19 (2.363)	1.78 (2.167)	
Median	1.50	1.59	1.36	1.04	
Min, Max	0.0, 6.8	0.0, 8.9	0.0, 8.6	0.0, 8.6	
C6D1 CFB					
n	15	34	47	84	
LS Mean (StdErr) [2]	-0.65 (0.528)	-0.86 (0.359)	-0.73 (0.292)	-1.04 (0.239)	
95% CI [2]	-1.71, 0.42	-1.59, -0.14	-1.31, -0.15	-1.51, -0.56	
Difference (95% CI) in CFB [2]		-0.22 (-1.41, 0.98)		-0.31 (-0.94, 0.32)	
p-value [3]		0.717		0.337	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.2a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	15	34	47	81	
Mean (StdDev)	2.70 (2.485)	2.14 (2.262)	2.13 (2.483)	1.75 (2.263)	
Median	2.36	1.61	1.23	0.64	
Min, Max	0.0, 7.1	0.0, 8.7	0.0, 8.6	0.0, 8.4	
C7D1 CFB					
n	15	34	47	81	
LS Mean (StdErr) [2]	-0.55 (0.564)	-1.09 (0.385)	-0.82 (0.321)	-1.02 (0.265)	
95% CI [2]	-1.68, 0.59	-1.86, -0.32	-1.45, -0.18	-1.54, -0.49	
Difference (95% CI) in CFB [2]		-0.54 (-1.81, 0.73)		-0.20 (-0.89, 0.49)	
Hedges'G (95% CI) in CFB		-0.24 (-0.88, 0.37)		-0.09 (-0.45, 0.28)	
p-value [3]		0.394		0.570	
					0.653

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	32	52	35	71	
Mean (StdDev)	5.35 (2.693)	5.45 (2.731)	5.72 (2.160)	5.73 (2.141)	
Median	5.60	5.91	5.92	6.00	
Min, Max	0.0, 9.4	0.0, 10.0	1.1, 10.0	0.5, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	32	51	35	68	
Mean (StdDev)	4.55 (2.766)	4.90 (2.644)	5.29 (2.381)	4.82 (2.536)	
Median	5.21	5.43	5.29	4.14	
Min, Max	0.0, 9.0	0.0, 9.9	0.7, 10.0	0.3, 10.0	
C2D1 CFB					
n	32	51	35	68	
LS Mean (StdErr) [2]	-0.86 (0.251)	-0.66 (0.218)	-0.30 (0.235)	-0.77 (0.179)	
95% CI [2]	-1.36, -0.37	-1.09, -0.23	-0.77, 0.17	-1.12, -0.41	
Difference (95% CI) in CFB [2]		0.20 (-0.36, 0.77)		-0.47 (-0.98, 0.05)	
p-value [3]		0.476		0.074	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	32	50	35	67	
Mean (StdDev)	4.37 (2.847)	4.50 (2.790)	5.26 (2.420)	4.56 (2.615)	
Median	4.96	4.68	5.64	4.00	
Min, Max	0.0, 9.1	0.0, 10.0	1.0, 10.0	0.0, 10.0	
C3D1 CFB					
n	32	50	35	67	
LS Mean (StdErr) [2]	-1.12 (0.284)	-1.11 (0.247)	-0.31 (0.288)	-1.01 (0.220)	
95% CI [2]	-1.68, -0.55	-1.60, -0.62	-0.88, 0.26	-1.45, -0.57	
Difference (95% CI) in CFB [2]		0.01 (-0.63, 0.65)		-0.70 (-1.33, -0.07)	
p-value [3]		0.984		0.030	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	30	50	34	67	
Mean (StdDev)	4.34 (2.990)	4.49 (2.911)	5.31 (2.451)	4.53 (2.722)	
Median	4.33	4.30	5.88	3.85	
Min, Max	0.0, 8.6	0.0, 10.0	0.9, 9.8	0.0, 10.0	
C4D1 CFB					
n	30	50	34	67	
LS Mean (StdErr) [2]	-1.20 (0.353)	-1.10 (0.295)	-0.21 (0.343)	-0.92 (0.260)	
95% CI [2]	-1.90, -0.49	-1.69, -0.51	-0.90, 0.47	-1.44, -0.41	
Difference (95% CI) in CFB [2]		0.10 (-0.68, 0.87)		-0.71 (-1.45, 0.04)	
p-value [3]		0.806		0.063	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	29	51	34	68	
Mean (StdDev)	4.51 (3.055)	4.12 (2.900)	5.14 (2.428)	4.36 (2.754)	
Median	4.46	4.38	5.68	4.29	
Min, Max	0.0, 9.0	0.0, 10.0	0.9, 9.8	0.0, 10.0	
C5D1 CFB					
n	29	51	34	68	
LS Mean (StdErr) [2]	-0.94 (0.347)	-1.33 (0.278)	-0.32 (0.387)	-1.03 (0.291)	
95% CI [2]	-1.63, -0.25	-1.88, -0.78	-1.08, 0.45	-1.61, -0.45	
Difference (95% CI) in CFB [2]		-0.39 (-1.16, 0.37)		-0.71 (-1.55, 0.13)	
p-value [3]		0.310		0.096	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	28	50	34	68	
Mean (StdDev)	4.34 (3.002)	4.06 (2.845)	5.19 (2.419)	4.13 (2.685)	
Median	4.65	3.71	5.70	3.96	
Min, Max	0.0, 9.1	0.0, 10.0	0.8, 9.6	0.0, 10.0	
C6D1 CFB					
n	28	50	34	68	
LS Mean (StdErr) [2]	-0.86 (0.384)	-1.30 (0.308)	-0.19 (0.371)	-1.21 (0.278)	
95% CI [2]	-1.63, -0.10	-1.92, -0.69	-0.93, 0.55	-1.77, -0.66	
Difference (95% CI) in CFB [2]		-0.44 (-1.30, 0.42)		-1.02 (-1.83, -0.22)	
p-value [3]		0.308		0.013	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	29	49	33	66	
Mean (StdDev)	4.34 (3.164)	3.98 (2.939)	5.11 (2.236)	4.05 (2.732)	
Median	4.93	3.78	5.43	3.52	
Min, Max	0.0, 9.3	0.0, 10.0	0.9, 9.4	0.0, 10.0	
C7D1 CFB					
n	29	49	33	66	
LS Mean (StdErr) [2]	-1.02 (0.394)	-1.38 (0.325)	-0.27 (0.390)	-1.25 (0.290)	
95% CI [2]	-1.81, -0.24	-2.03, -0.74	-1.05, 0.50	-1.82, -0.67	
Difference (95% CI) in CFB [2]		-0.36 (-1.24, 0.51)		-0.97 (-1.82, -0.13)	
Hedges'G (95% CI) in CFB		-0.16 (-0.63, 0.30)		-0.42 (-0.85, 0.00)	
p-value [3]		0.412		0.024	
					0.359

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	32	52	35	71	
Mean (StdDev)	3.96 (2.579)	4.51 (2.216)	4.37 (2.273)	3.91 (2.145)	
Median	3.76	4.14	4.50	3.86	
Min, Max	0.0, 9.6	0.6, 9.8	0.0, 8.7	0.0, 8.8	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	32	51	35	68	
Mean (StdDev)	3.10 (2.270)	3.65 (2.032)	3.64 (2.106)	3.16 (2.240)	
Median	3.00	3.50	3.71	2.62	
Min, Max	0.0, 8.9	0.1, 8.0	0.1, 7.5	0.0, 9.4	
C2D1 CFB					
n	32	51	35	68	
LS Mean (StdErr) [2]	-0.93 (0.222)	-0.92 (0.193)	-0.58 (0.223)	-0.61 (0.170)	
95% CI [2]	-1.37, -0.49	-1.30, -0.54	-1.03, -0.14	-0.95, -0.27	
Difference (95% CI) in CFB [2]		0.01 (-0.49, 0.51)		-0.02 (-0.51, 0.46)	
p-value [3]		0.971		0.924	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	32	50	35	67	
Mean (StdDev)	3.09 (2.313)	3.33 (2.128)	3.26 (2.178)	2.65 (2.187)	
Median	2.87	3.14	3.31	2.21	
Min, Max	0.0, 8.4	0.0, 8.3	0.0, 7.4	0.0, 8.3	
C3D1 CFB					
n	32	50	35	67	
LS Mean (StdErr) [2]	-0.97 (0.311)	-1.27 (0.270)	-0.84 (0.261)	-0.96 (0.199)	
95% CI [2]	-1.59, -0.35	-1.81, -0.73	-1.36, -0.32	-1.35, -0.56	
Difference (95% CI) in CFB [2]		-0.30 (-1.00, 0.40)		-0.12 (-0.69, 0.45)	
p-value [3]		0.402		0.682	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	30	50	34	67	
Mean (StdDev)	2.93 (2.262)	2.97 (2.268)	3.35 (2.114)	2.45 (2.135)	
Median	2.58	2.48	3.36	2.07	
Min, Max	0.0, 7.9	0.0, 8.4	0.0, 7.3	0.0, 9.1	
C4D1 CFB					
n	30	50	34	67	
LS Mean (StdErr) [2]	-1.26 (0.408)	-1.66 (0.341)	-0.81 (0.286)	-1.19 (0.217)	
95% CI [2]	-2.07, -0.45	-2.34, -0.98	-1.38, -0.24	-1.62, -0.76	
Difference (95% CI) in CFB [2]		-0.40 (-1.30, 0.50)		-0.38 (-1.00, 0.24)	
p-value [3]		0.377		0.231	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	29	51	34	68	
Mean (StdDev)	3.06 (2.427)	2.84 (2.236)	3.40 (2.003)	2.37 (2.322)	
Median	2.85	2.31	3.53	1.66	
Min, Max	0.0, 8.1	0.0, 8.8	0.0, 6.9	0.0, 9.4	
C5D1 CFB					
n	29	51	34	68	
LS Mean (StdErr) [2]	-1.17 (0.428)	-1.75 (0.343)	-0.66 (0.338)	-1.18 (0.255)	
95% CI [2]	-2.02, -0.32	-2.44, -1.07	-1.33, 0.01	-1.69, -0.68	
Difference (95% CI) in CFB [2]		-0.58 (-1.52, 0.36)		-0.52 (-1.25, 0.21)	
p-value [3]		0.224		0.162	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	28	50	34	68	
Mean (StdDev)	2.28 (2.068)	2.63 (2.284)	3.05 (2.082)	2.28 (2.266)	
Median	2.00	2.32	2.96	1.71	
Min, Max	0.0, 6.9	0.0, 8.9	0.0, 7.1	0.0, 9.6	
C6D1 CFB					
n	28	50	34	68	
LS Mean (StdErr) [2]	-1.64 (0.437)	-1.90 (0.350)	-0.97 (0.335)	-1.27 (0.251)	
95% CI [2]	-2.52, -0.77	-2.59, -1.20	-1.64, -0.31	-1.77, -0.78	
Difference (95% CI) in CFB [2]		-0.25 (-1.23, 0.72)		-0.30 (-1.03, 0.43)	
p-value [3]		0.610		0.417	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	29	49	33	66	
Mean (StdDev)	2.65 (2.560)	2.57 (2.171)	3.11 (2.081)	2.37 (2.279)	
Median	2.14	2.64	3.14	1.91	
Min, Max	0.0, 8.3	0.0, 8.6	0.0, 7.1	0.0, 9.4	
C7D1 CFB					
n	29	49	33	66	
LS Mean (StdErr) [2]	-1.41 (0.448)	-1.98 (0.369)	-0.98 (0.315)	-1.20 (0.234)	
95% CI [2]	-2.30, -0.52	-2.72, -1.25	-1.60, -0.35	-1.67, -0.74	
Difference (95% CI) in CFB [2]		-0.57 (-1.57, 0.43)		-0.23 (-0.91, 0.46)	
Hedges'G (95% CI) in CFB		-0.22 (-0.70, 0.24)		-0.12 (-0.55, 0.30)	
p-value [3]		0.257		0.513	
					0.519

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	32	52	35	71	
Mean (StdDev)	3.32 (2.513)	3.71 (2.600)	3.73 (2.445)	2.84 (2.413)	
Median	2.74	3.81	3.79	2.54	
Min, Max	0.0, 8.9	0.0, 9.0	0.0, 7.8	0.0, 8.9	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	32	51	35	68	
Mean (StdDev)	2.81 (2.465)	3.26 (2.296)	3.16 (2.282)	2.33 (2.344)	
Median	2.23	3.21	2.93	1.52	
Min, Max	0.0, 8.3	0.0, 8.2	0.0, 7.7	0.0, 8.8	
C2D1 CFB					
n	32	51	35	68	
LS Mean (StdErr) [2]	-0.44 (0.265)	-0.40 (0.230)	-0.50 (0.228)	-0.39 (0.174)	
95% CI [2]	-0.96, 0.09	-0.86, 0.05	-0.95, -0.05	-0.73, -0.04	
Difference (95% CI) in CFB [2]		0.03 (-0.56, 0.63)		0.11 (-0.39, 0.61)	
p-value [3]		0.910		0.655	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	32	50	35	67	
Mean (StdDev)	2.66 (2.423)	2.93 (2.273)	2.64 (2.223)	2.04 (2.232)	
Median	2.23	2.66	2.00	1.23	
Min, Max	0.0, 7.7	0.0, 7.9	0.0, 7.4	0.0, 8.9	
C3D1 CFB					
n	32	50	35	67	
LS Mean (StdErr) [2]	-0.59 (0.336)	-0.74 (0.292)	-1.06 (0.257)	-0.67 (0.196)	
95% CI [2]	-1.26, 0.08	-1.32, -0.16	-1.57, -0.55	-1.06, -0.28	
Difference (95% CI) in CFB [2]		-0.15 (-0.91, 0.61)		0.39 (-0.17, 0.95)	
p-value [3]		0.694		0.169	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	30	50	34	67	
Mean (StdDev)	2.67 (2.261)	2.48 (2.274)	2.80 (2.233)	1.90 (2.212)	
Median	1.93	1.93	2.89	1.08	
Min, Max	0.0, 7.4	0.0, 8.4	0.0, 7.0	0.0, 9.2	
C4D1 CFB					
n	30	50	34	67	
LS Mean (StdErr) [2]	-0.74 (0.394)	-1.22 (0.330)	-1.00 (0.293)	-0.87 (0.222)	
95% CI [2]	-1.53, 0.04	-1.88, -0.57	-1.58, -0.42	-1.31, -0.43	
Difference (95% CI) in CFB [2]		-0.48 (-1.35, 0.39)		0.13 (-0.51, 0.77)	
p-value [3]		0.275		0.685	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	29	51	34	68	
Mean (StdDev)	2.86 (2.514)	2.34 (2.315)	2.74 (1.952)	1.96 (2.203)	
Median	2.85	1.64	2.50	1.21	
Min, Max	0.0, 8.5	0.0, 8.9	0.0, 6.6	0.0, 8.4	
C5D1 CFB					
n	29	51	34	68	
LS Mean (StdErr) [2]	-0.67 (0.403)	-1.38 (0.323)	-0.95 (0.339)	-0.71 (0.255)	
95% CI [2]	-1.47, 0.14	-2.02, -0.73	-1.62, -0.27	-1.22, -0.20	
Difference (95% CI) in CFB [2]		-0.71 (-1.60, 0.18)		0.24 (-0.50, 0.97)	
p-value [3]		0.115		0.526	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	28	50	34	68	
Mean (StdDev)	2.40 (2.351)	2.05 (2.310)	2.50 (1.917)	1.79 (2.095)	
Median	1.79	1.50	2.36	1.36	
Min, Max	0.0, 7.9	0.0, 8.9	0.0, 6.7	0.0, 9.9	
C6D1 CFB					
n	28	50	34	68	
LS Mean (StdErr) [2]	-1.03 (0.431)	-1.59 (0.346)	-1.26 (0.310)	-0.96 (0.232)	
95% CI [2]	-1.89, -0.17	-2.28, -0.90	-1.87, -0.64	-1.42, -0.50	
Difference (95% CI) in CFB [2]		-0.56 (-1.52, 0.40)		0.29 (-0.38, 0.97)	
p-value [3]		0.249		0.390	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	29	49	33	66	
Mean (StdDev)	2.50 (2.442)	2.05 (2.227)	2.62 (2.140)	1.86 (2.163)	
Median	2.08	1.45	2.55	1.23	
Min, Max	0.0, 7.7	0.0, 8.3	0.0, 6.3	0.0, 9.5	
C7D1 CFB					
n	29	49	33	66	
LS Mean (StdErr) [2]	-1.06 (0.448)	-1.59 (0.369)	-0.97 (0.357)	-0.81 (0.265)	
95% CI [2]	-1.95, -0.17	-2.33, -0.85	-1.68, -0.26	-1.34, -0.28	
Difference (95% CI) in CFB [2]		-0.53 (-1.52, 0.47)		0.16 (-0.62, 0.93)	
Hedges'G (95% CI) in CFB		-0.21 (-0.68, 0.25)		0.07 (-0.35, 0.50)	
p-value [3]		0.294		0.687	
					0.259

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	32	52	35	71	
Mean (StdDev)	6.49 (2.979)	5.49 (3.365)	5.62 (3.035)	5.58 (2.757)	
Median	7.00	5.86	6.07	6.14	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 10.0	0.0, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	32	51	35	68	
Mean (StdDev)	6.23 (2.801)	4.84 (3.113)	5.07 (2.837)	4.50 (2.475)	
Median	6.66	5.00	5.21	4.62	
Min, Max	0.0, 10.0	0.0, 9.9	0.0, 10.0	0.0, 10.0	
C2D1 CFB					
n	32	51	35	68	
LS Mean (StdErr) [2]	-0.21 (0.210)	-0.62 (0.182)	-0.44 (0.254)	-1.00 (0.194)	
95% CI [2]	-0.62, 0.21	-0.98, -0.25	-0.94, 0.07	-1.39, -0.62	
Difference (95% CI) in CFB [2]		-0.41 (-0.88, 0.06)		-0.56 (-1.12, -0.01)	
p-value [3]		0.088		0.046	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	32	50	35	67	
Mean (StdDev)	6.35 (2.775)	4.41 (3.044)	4.87 (2.892)	4.07 (2.234)	
Median	6.25	4.00	5.00	4.00	
Min, Max	0.0, 10.0	0.0, 9.8	0.0, 10.0	0.0, 9.0	
C3D1 CFB					
n	32	50	35	67	
LS Mean (StdErr) [2]	0.02 (0.231)	-0.93 (0.201)	-0.54 (0.331)	-1.37 (0.253)	
95% CI [2]	-0.44, 0.48	-1.33, -0.53	-1.19, 0.12	-1.88, -0.87	
Difference (95% CI) in CFB [2]		-0.96 (-1.48, -0.43)		-0.84 (-1.56, -0.11)	
p-value [3]		<0.001		0.024	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	30	50	34	67	
Mean (StdDev)	6.37 (2.940)	4.18 (2.935)	4.73 (2.728)	3.85 (2.324)	
Median	6.77	3.89	4.79	3.71	
Min, Max	0.0, 10.0	0.0, 9.3	0.0, 10.0	0.0, 9.4	
C4D1 CFB					
n	30	50	34	67	
LS Mean (StdErr) [2]	0.08 (0.256)	-1.03 (0.214)	-0.39 (0.345)	-1.48 (0.261)	
95% CI [2]	-0.43, 0.59	-1.46, -0.60	-1.07, 0.30	-2.00, -0.96	
Difference (95% CI) in CFB [2]		-1.11 (-1.67, -0.54)		-1.09 (-1.84, -0.34)	
p-value [3]		<0.001		0.005	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	29	51	34	68	
Mean (StdDev)	6.36 (3.019)	3.79 (2.886)	4.58 (2.587)	3.74 (2.329)	
Median	7.14	3.07	4.29	3.39	
Min, Max	0.0, 10.0	0.0, 9.3	0.0, 10.0	0.0, 9.9	
C5D1 CFB					
n	29	51	34	68	
LS Mean (StdErr) [2]	-0.02 (0.305)	-1.51 (0.245)	-0.56 (0.361)	-1.54 (0.272)	
95% CI [2]	-0.63, 0.58	-2.00, -1.02	-1.28, 0.16	-2.08, -1.01	
Difference (95% CI) in CFB [2]		-1.49 (-2.16, -0.81)		-0.99 (-1.77, -0.20)	
p-value [3]		<0.0001		0.014	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	28	50	34	68	
Mean (StdDev)	6.38 (2.875)	3.56 (2.699)	4.73 (2.773)	3.62 (2.506)	
Median	6.37	3.24	4.43	3.19	
Min, Max	0.0, 10.0	0.0, 9.1	0.0, 10.0	0.0, 10.0	
C6D1 CFB					
n	28	50	34	68	
LS Mean (StdErr) [2]	-0.05 (0.353)	-1.63 (0.283)	-0.31 (0.425)	-1.59 (0.318)	
95% CI [2]	-0.75, 0.65	-2.19, -1.07	-1.15, 0.53	-2.22, -0.96	
Difference (95% CI) in CFB [2]		-1.58 (-2.37, -0.80)		-1.28 (-2.20, -0.36)	
p-value [3]		<0.001		0.007	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	29	49	33	66	
Mean (StdDev)	6.35 (2.942)	3.44 (2.786)	4.77 (2.587)	3.65 (2.588)	
Median	5.93	3.15	4.14	3.25	
Min, Max	0.0, 10.0	0.0, 9.0	0.0, 10.0	0.0, 10.0	
C7D1 CFB					
n	29	49	33	66	
LS Mean (StdErr) [2]	-0.18 (0.347)	-1.87 (0.286)	-0.38 (0.449)	-1.55 (0.333)	
95% CI [2]	-0.87, 0.52	-2.44, -1.30	-1.27, 0.51	-2.21, -0.89	
Difference (95% CI) in CFB [2]		-1.69 (-2.47, -0.92)		-1.17 (-2.14, -0.20)	
Hedges'G (95% CI) in CFB		-0.86 (-1.37, -0.40)		-0.44 (-0.87, -0.02)	
p-value [3]		<0.0001		0.019	
					0.409

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	32	52	35	71	
Mean (StdDev)	6.23 (2.632)	5.52 (2.639)	5.73 (2.667)	5.40 (2.722)	
Median	6.79	5.89	5.93	5.36	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 10.0	0.0, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	32	51	35	68	
Mean (StdDev)	5.48 (2.903)	4.58 (2.318)	5.11 (2.609)	4.21 (2.410)	
Median	6.07	4.43	5.31	4.32	
Min, Max	0.0, 9.8	0.0, 9.9	0.0, 10.0	0.0, 9.6	
C2D1 CFB					
n	32	51	35	68	
LS Mean (StdErr) [2]	-1.08 (0.301)	-1.28 (0.261)	-0.45 (0.306)	-1.07 (0.234)	
95% CI [2]	-1.68, -0.48	-1.80, -0.76	-1.06, 0.16	-1.53, -0.61	
Difference (95% CI) in CFB [2]		-0.20 (-0.87, 0.48)		-0.62 (-1.29, 0.05)	
p-value [3]		0.563		0.069	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	32	50	35	67	
Mean (StdDev)	5.30 (3.003)	3.83 (2.307)	4.73 (2.485)	3.56 (2.547)	
Median	5.65	3.68	4.77	3.14	
Min, Max	0.0, 9.9	0.0, 8.2	0.0, 10.0	0.0, 9.7	
C3D1 CFB					
n	32	50	35	67	
LS Mean (StdErr) [2]	-1.02 (0.327)	-1.72 (0.284)	-0.73 (0.409)	-1.63 (0.312)	
95% CI [2]	-1.67, -0.37	-2.29, -1.16	-1.54, 0.08	-2.25, -1.01	
Difference (95% CI) in CFB [2]		-0.70 (-1.44, 0.04)		-0.90 (-1.79, -0.00)	
p-value [3]		0.062		0.049	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	30	50	34	67	
Mean (StdDev)	5.12 (3.196)	3.53 (2.369)	4.72 (2.434)	3.37 (2.680)	
Median	5.64	3.48	5.00	3.00	
Min, Max	0.0, 9.8	0.0, 9.1	0.0, 10.0	0.0, 10.0	
C4D1 CFB					
n	30	50	34	67	
LS Mean (StdErr) [2]	-1.49 (0.424)	-2.14 (0.355)	-0.68 (0.463)	-1.83 (0.351)	
95% CI [2]	-2.33, -0.64	-2.85, -1.43	-1.60, 0.24	-2.53, -1.14	
Difference (95% CI) in CFB [2]		-0.65 (-1.58, 0.29)		-1.15 (-2.16, -0.14)	
p-value [3]		0.170		0.025	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	29	51	34	68	
Mean (StdDev)	5.39 (3.115)	3.17 (2.200)	4.70 (2.187)	3.20 (2.746)	
Median	5.79	3.00	4.53	2.77	
Min, Max	0.0, 10.0	0.0, 8.3	0.0, 10.0	0.0, 10.0	
C5D1 CFB					
n	29	51	34	68	
LS Mean (StdErr) [2]	-1.30 (0.436)	-2.49 (0.350)	-0.54 (0.478)	-1.79 (0.360)	
95% CI [2]	-2.17, -0.43	-3.18, -1.79	-1.49, 0.41	-2.51, -1.08	
Difference (95% CI) in CFB [2]		-1.19 (-2.15, -0.23)		-1.25 (-2.29, -0.21)	
p-value [3]		0.016		0.019	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	28	50	34	68	
Mean (StdDev)	5.10 (3.044)	3.21 (2.344)	4.80 (2.360)	3.04 (2.695)	
Median	4.88	3.00	5.00	2.34	
Min, Max	0.0, 10.0	0.0, 8.2	0.0, 10.0	0.0, 10.0	
C6D1 CFB					
n	28	50	34	68	
LS Mean (StdErr) [2]	-1.60 (0.454)	-2.48 (0.364)	-0.52 (0.482)	-2.07 (0.361)	
95% CI [2]	-2.50, -0.69	-3.21, -1.76	-1.48, 0.44	-2.78, -1.35	
Difference (95% CI) in CFB [2]		-0.89 (-1.90, 0.13)		-1.55 (-2.59, -0.50)	
p-value [3]		0.085		0.004	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	29	49	33	66	
Mean (StdDev)	5.19 (3.141)	3.01 (2.241)	4.93 (1.937)	3.07 (2.702)	
Median	5.22	2.92	4.75	2.45	
Min, Max	0.0, 10.0	0.0, 9.0	1.5, 10.0	0.0, 10.0	
C7D1 CFB					
n	29	49	33	66	
LS Mean (StdErr) [2]	-1.56 (0.484)	-2.68 (0.399)	-0.43 (0.506)	-1.99 (0.375)	
95% CI [2]	-2.52, -0.59	-3.47, -1.88	-1.44, 0.57	-2.74, -1.25	
Difference (95% CI) in CFB [2]		-1.12 (-2.20, -0.04)		-1.56 (-2.66, -0.46)	
Hedges'G (95% CI) in CFB		-0.41 (-0.89, 0.05)		-0.52 (-0.96, -0.10)	
p-value [3]		0.041		0.006	
					0.611

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	32	52	35	71	
Mean (StdDev)	6.42 (2.173)	5.62 (2.210)	5.50 (2.814)	5.22 (2.546)	
Median	6.24	5.41	5.36	5.50	
Min, Max	1.1, 10.0	0.0, 10.0	0.0, 10.0	0.0, 9.9	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	32	51	35	68	
Mean (StdDev)	5.81 (2.197)	4.80 (2.164)	5.00 (2.955)	4.60 (2.675)	
Median	5.76	5.00	4.64	4.63	
Min, Max	2.1, 10.0	0.0, 8.6	0.0, 10.0	0.0, 10.0	
C2D1 CFB					
n	32	51	35	68	
LS Mean (StdErr) [2]	-0.71 (0.246)	-0.93 (0.213)	-0.42 (0.310)	-0.58 (0.237)	
95% CI [2]	-1.20, -0.22	-1.35, -0.50	-1.04, 0.19	-1.05, -0.11	
Difference (95% CI) in CFB [2]		-0.21 (-0.77, 0.34)		-0.16 (-0.84, 0.52)	
p-value [3]		0.443		0.638	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	32	50	35	67	
Mean (StdDev)	5.55 (2.703)	4.26 (2.342)	4.88 (2.878)	4.05 (2.635)	
Median	5.63	4.25	4.69	4.00	
Min, Max	0.0, 9.8	0.0, 9.1	0.0, 10.0	0.0, 10.0	
C3D1 CFB					
n	32	50	35	67	
LS Mean (StdErr) [2]	-0.94 (0.323)	-1.44 (0.281)	-0.42 (0.358)	-1.02 (0.273)	
95% CI [2]	-1.58, -0.29	-2.00, -0.88	-1.13, 0.29	-1.56, -0.48	
Difference (95% CI) in CFB [2]		-0.51 (-1.24, 0.22)		-0.60 (-1.38, 0.18)	
p-value [3]		0.169		0.131	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	30	50	34	67	
Mean (StdDev)	5.36 (2.780)	4.06 (2.387)	4.99 (2.941)	3.82 (2.637)	
Median	5.68	4.04	4.46	3.54	
Min, Max	0.1, 9.8	0.0, 9.3	0.0, 10.0	0.0, 10.0	
C4D1 CFB					
n	30	50	34	67	
LS Mean (StdErr) [2]	-1.32 (0.385)	-1.82 (0.322)	-0.35 (0.401)	-1.27 (0.305)	
95% CI [2]	-2.09, -0.56	-2.46, -1.18	-1.15, 0.45	-1.88, -0.67	
Difference (95% CI) in CFB [2]		-0.49 (-1.34, 0.35)		-0.92 (-1.80, -0.05)	
p-value [3]		0.250		0.038	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	29	51	34	68	
Mean (StdDev)	5.37 (2.775)	3.84 (2.264)	5.06 (2.934)	3.65 (2.745)	
Median	5.46	3.92	4.44	3.62	
Min, Max	0.2, 10.0	0.0, 8.8	0.0, 10.0	0.0, 9.8	
C5D1 CFB					
n	29	51	34	68	
LS Mean (StdErr) [2]	-1.26 (0.393)	-1.95 (0.316)	-0.40 (0.466)	-1.51 (0.350)	
95% CI [2]	-2.04, -0.48	-2.58, -1.32	-1.32, 0.53	-2.20, -0.81	
Difference (95% CI) in CFB [2]		-0.69 (-1.55, 0.18)		-1.11 (-2.12, -0.10)	
p-value [3]		0.119		0.032	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	28	50	34	68	
Mean (StdDev)	5.32 (2.731)	3.75 (2.325)	4.83 (3.023)	3.48 (2.765)	
Median	5.42	3.61	4.39	3.18	
Min, Max	0.1, 10.0	0.0, 9.1	0.0, 10.0	0.0, 10.0	
C6D1 CFB					
n	28	50	34	68	
LS Mean (StdErr) [2]	-1.42 (0.433)	-2.09 (0.347)	-0.60 (0.470)	-1.66 (0.351)	
95% CI [2]	-2.29, -0.56	-2.78, -1.40	-1.54, 0.33	-2.35, -0.96	
Difference (95% CI) in CFB [2]		-0.66 (-1.63, 0.30)		-1.05 (-2.07, -0.03)	
p-value [3]		0.175		0.043	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	29	49	33	66	
Mean (StdDev)	5.25 (2.870)	3.34 (2.383)	5.00 (2.831)	3.37 (2.683)	
Median	5.79	3.23	4.44	2.61	
Min, Max	0.4, 10.0	0.0, 9.5	0.0, 10.0	0.0, 10.0	
C7D1 CFB					
n	29	49	33	66	
LS Mean (StdErr) [2]	-1.52 (0.475)	-2.47 (0.391)	-0.41 (0.472)	-1.59 (0.350)	
95% CI [2]	-2.46, -0.57	-3.25, -1.69	-1.35, 0.52	-2.28, -0.89	
Difference (95% CI) in CFB [2]		-0.95 (-2.00, 0.11)		-1.18 (-2.20, -0.15)	
Hedges'G (95% CI) in CFB		-0.35 (-0.83, 0.11)		-0.42 (-0.85, 0.00)	
p-value [3]		0.077		0.025	
					0.795

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	32	52	35	71	
Mean (StdDev)	6.64 (2.171)	6.83 (1.909)	6.92 (1.855)	7.03 (2.051)	
Median	6.63	7.01	6.79	7.21	
Min, Max	0.0, 10.0	0.1, 10.0	3.3, 10.0	1.5, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	32	51	35	68	
Mean (StdDev)	6.10 (2.073)	6.30 (2.097)	6.62 (1.787)	6.24 (2.293)	
Median	6.08	6.29	6.57	6.41	
Min, Max	2.3, 10.0	0.1, 10.0	2.8, 9.9	0.7, 10.0	
C2D1 CFB					
n	32	51	35	68	
LS Mean (StdErr) [2]	-0.63 (0.216)	-0.62 (0.187)	-0.28 (0.250)	-0.79 (0.191)	
95% CI [2]	-1.06, -0.20	-0.99, -0.25	-0.77, 0.22	-1.17, -0.41	
Difference (95% CI) in CFB [2]		0.01 (-0.47, 0.50)		-0.52 (-1.06, 0.03)	
p-value [3]		0.964		0.063	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	32	50	35	67	
Mean (StdDev)	5.88 (2.492)	5.87 (2.110)	6.17 (2.057)	5.78 (2.456)	
Median	5.74	5.88	6.07	5.64	
Min, Max	0.3, 10.0	1.4, 10.0	2.4, 9.9	0.2, 10.0	
C3D1 CFB					
n	32	50	35	67	
LS Mean (StdErr) [2]	-0.79 (0.296)	-0.96 (0.257)	-0.76 (0.314)	-1.25 (0.240)	
95% CI [2]	-1.38, -0.20	-1.48, -0.45	-1.38, -0.13	-1.73, -0.78	
Difference (95% CI) in CFB [2]		-0.17 (-0.84, 0.50)		-0.50 (-1.18, 0.19)	
p-value [3]		0.610		0.155	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	30	50	34	67	
Mean (StdDev)	5.63 (2.702)	5.43 (2.341)	6.01 (2.089)	5.59 (2.589)	
Median	5.58	5.44	6.11	5.85	
Min, Max	0.2, 10.0	0.5, 10.0	2.1, 9.9	0.0, 10.0	
C4D1 CFB					
n	30	50	34	67	
LS Mean (StdErr) [2]	-1.23 (0.368)	-1.55 (0.308)	-0.81 (0.381)	-1.39 (0.289)	
95% CI [2]	-1.97, -0.50	-2.16, -0.94	-1.56, -0.05	-1.97, -0.82	
Difference (95% CI) in CFB [2]		-0.32 (-1.13, 0.49)		-0.59 (-1.42, 0.24)	
p-value [3]		0.437		0.163	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	29	51	34	68	
Mean (StdDev)	5.50 (2.835)	5.34 (2.142)	5.89 (2.032)	5.58 (2.666)	
Median	5.55	5.38	5.79	5.89	
Min, Max	0.6, 10.0	0.3, 10.0	2.5, 9.9	0.0, 10.0	
C5D1 CFB					
n	29	51	34	68	
LS Mean (StdErr) [2]	-1.35 (0.351)	-1.61 (0.281)	-0.79 (0.415)	-1.28 (0.312)	
95% CI [2]	-2.05, -0.65	-2.17, -1.05	-1.61, 0.04	-1.90, -0.66	
Difference (95% CI) in CFB [2]		-0.26 (-1.03, 0.51)		-0.50 (-1.40, 0.40)	
p-value [3]		0.503		0.277	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	28	50	34	68	
Mean (StdDev)	5.61 (2.857)	5.14 (2.515)	5.95 (1.947)	5.25 (2.874)	
Median	5.15	5.14	6.04	5.26	
Min, Max	0.4, 10.0	0.0, 10.0	2.0, 10.0	0.0, 10.0	
C6D1 CFB					
n	28	50	34	68	
LS Mean (StdErr) [2]	-1.16 (0.410)	-1.78 (0.328)	-0.72 (0.418)	-1.57 (0.313)	
95% CI [2]	-1.97, -0.34	-2.43, -1.12	-1.55, 0.11	-2.19, -0.95	
Difference (95% CI) in CFB [2]		-0.62 (-1.53, 0.29)		-0.85 (-1.76, 0.06)	
p-value [3]		0.180		0.066	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	29	49	33	66	
Mean (StdDev)	5.48 (2.979)	4.98 (2.417)	6.00 (1.982)	5.09 (2.799)	
Median	5.64	5.22	5.79	5.07	
Min, Max	0.2, 10.0	0.0, 10.0	2.6, 10.0	0.0, 10.0	
C7D1 CFB					
n	29	49	33	66	
LS Mean (StdErr) [2]	-1.41 (0.419)	-2.02 (0.345)	-0.57 (0.419)	-1.60 (0.311)	
95% CI [2]	-2.25, -0.58	-2.71, -1.34	-1.40, 0.26	-2.22, -0.99	
Difference (95% CI) in CFB [2]		-0.61 (-1.54, 0.32)		-1.03 (-1.94, -0.12)	
Hedges'G (95% CI) in CFB		-0.26 (-0.73, 0.21)		-0.41 (-0.85, 0.01)	
p-value [3]		0.197		0.026	
					0.586

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	32	52	35	71	
Mean (StdDev)	3.87 (2.942)	3.64 (2.621)	3.58 (2.651)	4.20 (2.947)	
Median	3.12	4.19	3.07	3.86	
Min, Max	0.0, 9.3	0.0, 8.9	0.0, 8.4	0.0, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	32	51	35	68	
Mean (StdDev)	3.08 (2.766)	3.18 (2.403)	3.33 (2.629)	3.51 (2.858)	
Median	2.62	3.00	3.07	3.04	
Min, Max	0.0, 8.4	0.0, 8.1	0.0, 8.7	0.0, 10.0	
C2D1 CFB					
n	32	51	35	68	
LS Mean (StdErr) [2]	-0.85 (0.234)	-0.57 (0.203)	-0.14 (0.293)	-0.61 (0.224)	
95% CI [2]	-1.31, -0.38	-0.97, -0.17	-0.72, 0.44	-1.06, -0.17	
Difference (95% CI) in CFB [2]		0.28 (-0.25, 0.80)		-0.47 (-1.11, 0.17)	
p-value [3]		0.296		0.146	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	32	50	35	67	
Mean (StdDev)	3.02 (2.649)	2.94 (2.438)	2.76 (2.540)	2.99 (2.899)	
Median	2.54	2.39	1.92	2.08	
Min, Max	0.0, 8.1	0.0, 8.1	0.0, 7.6	0.0, 10.0	
C3D1 CFB					
n	32	50	35	67	
LS Mean (StdErr) [2]	-0.82 (0.302)	-0.71 (0.262)	-0.66 (0.324)	-1.08 (0.248)	
95% CI [2]	-1.42, -0.22	-1.24, -0.19	-1.30, -0.01	-1.57, -0.59	
Difference (95% CI) in CFB [2]		0.11 (-0.57, 0.79)		-0.42 (-1.13, 0.29)	
p-value [3]		0.748		0.241	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	30	50	34	67	
Mean (StdDev)	3.07 (2.695)	2.75 (2.500)	3.04 (2.651)	3.00 (2.932)	
Median	2.36	2.01	2.79	2.23	
Min, Max	0.0, 8.1	0.0, 8.1	0.0, 9.9	0.0, 10.0	
C4D1 CFB					
n	30	50	34	67	
LS Mean (StdErr) [2]	-0.92 (0.398)	-0.94 (0.333)	-0.36 (0.372)	-1.07 (0.282)	
95% CI [2]	-1.72, -0.13	-1.61, -0.28	-1.09, 0.38	-1.63, -0.51	
Difference (95% CI) in CFB [2]		-0.02 (-0.89, 0.86)		-0.72 (-1.53, 0.09)	
p-value [3]		0.967		0.081	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	29	51	34	68	
Mean (StdDev)	3.15 (2.754)	2.60 (2.516)	2.98 (2.513)	2.83 (2.783)	
Median	2.36	1.69	2.51	2.11	
Min, Max	0.0, 8.0	0.0, 8.0	0.0, 9.6	0.0, 10.0	
C5D1 CFB					
n	29	51	34	68	
LS Mean (StdErr) [2]	-0.84 (0.366)	-1.02 (0.294)	-0.29 (0.380)	-1.11 (0.286)	
95% CI [2]	-1.57, -0.12	-1.61, -0.44	-1.04, 0.46	-1.68, -0.55	
Difference (95% CI) in CFB [2]		-0.18 (-0.98, 0.63)		-0.82 (-1.65, 0.00)	
p-value [3]		0.663		0.051	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	28	50	34	68	
Mean (StdDev)	2.90 (2.745)	2.38 (2.321)	2.82 (2.513)	2.51 (2.747)	
Median	1.79	1.86	2.07	1.79	
Min, Max	0.0, 8.3	0.0, 8.2	0.0, 8.6	0.0, 10.0	
C6D1 CFB					
n	28	50	34	68	
LS Mean (StdErr) [2]	-1.09 (0.414)	-1.16 (0.332)	-0.51 (0.392)	-1.44 (0.293)	
95% CI [2]	-1.92, -0.27	-1.82, -0.50	-1.29, 0.27	-2.02, -0.86	
Difference (95% CI) in CFB [2]		-0.07 (-0.99, 0.86)		-0.93 (-1.78, -0.08)	
p-value [3]		0.885		0.033	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	29	49	33	66	
Mean (StdDev)	2.95 (2.866)	2.35 (2.346)	2.79 (2.503)	2.56 (2.757)	
Median	1.86	1.62	2.00	2.00	
Min, Max	0.0, 8.8	0.0, 8.3	0.0, 10.0	0.0, 10.0	
C7D1 CFB					
n	29	49	33	66	
LS Mean (StdErr) [2]	-1.24 (0.438)	-1.23 (0.361)	-0.40 (0.403)	-1.35 (0.299)	
95% CI [2]	-2.11, -0.37	-1.95, -0.51	-1.20, 0.40	-1.94, -0.76	
Difference (95% CI) in CFB [2]		0.02 (-0.96, 0.99)		-0.95 (-1.82, -0.07)	
Hedges'G (95% CI) in CFB		0.01 (-0.46, 0.47)		-0.39 (-0.83, 0.02)	
p-value [3]		0.974		0.034	
					0.158

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	32	52	35	71	
Mean (StdDev)	5.68 (2.713)	5.78 (2.182)	4.82 (2.614)	5.58 (2.616)	
Median	5.84	5.95	5.07	5.79	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 9.4	0.0, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	32	51	35	68	
Mean (StdDev)	4.85 (2.825)	5.24 (2.383)	4.55 (2.485)	4.76 (2.895)	
Median	4.74	5.57	4.14	4.50	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 9.5	0.0, 10.0	
C2D1 CFB					
n	32	51	35	68	
LS Mean (StdErr) [2]	-0.99 (0.210)	-0.74 (0.182)	-0.08 (0.215)	-0.67 (0.164)	
95% CI [2]	-1.41, -0.57	-1.10, -0.37	-0.51, 0.35	-0.99, -0.34	
Difference (95% CI) in CFB [2]		0.25 (-0.22, 0.72)		-0.59 (-1.05, -0.12)	
p-value [3]		0.290		0.015	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	32	50	35	67	
Mean (StdDev)	4.87 (2.822)	4.70 (2.555)	4.15 (2.534)	4.56 (2.924)	
Median	4.52	4.82	3.86	4.31	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 9.2	0.0, 10.0	
C3D1 CFB					
n	32	50	35	67	
LS Mean (StdErr) [2]	-0.91 (0.270)	-1.16 (0.235)	-0.51 (0.271)	-0.96 (0.207)	
95% CI [2]	-1.44, -0.37	-1.63, -0.69	-1.05, 0.02	-1.37, -0.55	
Difference (95% CI) in CFB [2]		-0.26 (-0.86, 0.35)		-0.45 (-1.04, 0.14)	
p-value [3]		0.406		0.137	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	30	50	34	67	
Mean (StdDev)	4.40 (2.989)	4.39 (2.553)	4.20 (2.562)	4.42 (3.091)	
Median	4.32	4.24	4.04	4.15	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 9.9	0.0, 10.0	
C4D1 CFB					
n	30	50	34	67	
LS Mean (StdErr) [2]	-1.47 (0.355)	-1.60 (0.297)	-0.48 (0.317)	-0.99 (0.241)	
95% CI [2]	-2.18, -0.76	-2.19, -1.01	-1.11, 0.15	-1.46, -0.51	
Difference (95% CI) in CFB [2]		-0.13 (-0.92, 0.65)		-0.51 (-1.20, 0.18)	
p-value [3]		0.736		0.145	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	29	51	34	68	
Mean (StdDev)	4.06 (3.078)	4.19 (2.533)	4.10 (2.531)	4.50 (3.128)	
Median	3.82	4.43	3.64	4.65	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 9.9	0.0, 10.0	
C5D1 CFB					
n	29	51	34	68	
LS Mean (StdErr) [2]	-1.73 (0.387)	-1.69 (0.311)	-0.45 (0.344)	-0.80 (0.259)	
95% CI [2]	-2.50, -0.96	-2.31, -1.07	-1.13, 0.24	-1.31, -0.28	
Difference (95% CI) in CFB [2]		0.04 (-0.81, 0.89)		-0.35 (-1.10, 0.40)	
p-value [3]		0.927		0.356	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	28	50	34	68	
Mean (StdDev)	4.23 (3.093)	4.05 (2.629)	4.12 (2.407)	4.28 (3.164)	
Median	3.93	4.36	3.71	4.07	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 9.6	0.0, 10.0	
C6D1 CFB					
n	28	50	34	68	
LS Mean (StdErr) [2]	-1.48 (0.375)	-1.83 (0.301)	-0.39 (0.340)	-0.96 (0.254)	
95% CI [2]	-2.23, -0.73	-2.43, -1.23	-1.07, 0.28	-1.46, -0.46	
Difference (95% CI) in CFB [2]		-0.35 (-1.19, 0.48)		-0.57 (-1.30, 0.17)	
p-value [3]		0.402		0.130	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	29	49	33	66	
Mean (StdDev)	4.40 (3.179)	3.93 (2.703)	4.01 (2.517)	4.26 (3.170)	
Median	4.21	4.15	3.71	4.46	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 10.0	0.0, 10.0	
C7D1 CFB					
n	29	49	33	66	
LS Mean (StdErr) [2]	-1.45 (0.395)	-2.02 (0.326)	-0.43 (0.357)	-0.95 (0.265)	
95% CI [2]	-2.24, -0.66	-2.67, -1.37	-1.14, 0.28	-1.48, -0.43	
Difference (95% CI) in CFB [2]		-0.57 (-1.45, 0.31)		-0.52 (-1.30, 0.25)	
Hedges'G (95% CI) in CFB		-0.25 (-0.73, 0.21)		-0.25 (-0.68, 0.17)	
p-value [3]		0.202		0.182	
					0.873

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	32	52	35	71	
Mean (StdDev)	4.21 (2.929)	4.28 (2.138)	4.29 (2.526)	4.36 (2.710)	
Median	4.96	4.22	4.36	3.93	
Min, Max	0.0, 9.9	0.0, 8.6	0.4, 8.9	0.0, 9.9	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	32	51	35	68	
Mean (StdDev)	3.87 (2.736)	3.71 (2.162)	3.97 (2.484)	3.73 (2.609)	
Median	3.68	3.79	4.00	3.43	
Min, Max	0.0, 9.1	0.1, 8.4	0.0, 8.5	0.0, 10.0	
C2D1 CFB					
n	32	51	35	68	
LS Mean (StdErr) [2]	-0.52 (0.233)	-0.73 (0.202)	-0.21 (0.251)	-0.53 (0.192)	
95% CI [2]	-0.98, -0.05	-1.14, -0.33	-0.71, 0.29	-0.91, -0.15	
Difference (95% CI) in CFB [2]		-0.22 (-0.74, 0.31)		-0.32 (-0.87, 0.22)	
p-value [3]		0.410		0.245	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	32	50	35	67	
Mean (StdDev)	3.56 (2.704)	3.37 (2.162)	3.55 (2.469)	3.35 (2.564)	
Median	2.54	3.04	3.29	2.79	
Min, Max	0.0, 9.1	0.1, 8.2	0.0, 8.0	0.0, 10.0	
C3D1 CFB					
n	32	50	35	67	
LS Mean (StdErr) [2]	-0.78 (0.319)	-1.05 (0.277)	-0.50 (0.313)	-0.78 (0.239)	
95% CI [2]	-1.41, -0.15	-1.60, -0.50	-1.12, 0.12	-1.25, -0.30	
Difference (95% CI) in CFB [2]		-0.27 (-0.99, 0.45)		-0.27 (-0.96, 0.41)	
p-value [3]		0.460		0.430	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	30	50	34	67	
Mean (StdDev)	3.26 (2.481)	3.09 (2.165)	3.95 (2.449)	3.31 (2.501)	
Median	2.89	2.88	4.11	2.82	
Min, Max	0.0, 8.1	0.0, 7.5	0.0, 8.4	0.0, 9.9	
C4D1 CFB					
n	30	50	34	67	
LS Mean (StdErr) [2]	-1.11 (0.379)	-1.27 (0.317)	-0.32 (0.335)	-0.97 (0.254)	
95% CI [2]	-1.87, -0.36	-1.90, -0.64	-0.99, 0.34	-1.47, -0.46	
Difference (95% CI) in CFB [2]		-0.16 (-0.99, 0.68)		-0.65 (-1.37, 0.08)	
p-value [3]		0.709		0.081	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	29	51	34	68	
Mean (StdDev)	3.53 (2.648)	3.00 (2.094)	3.60 (2.360)	3.17 (2.529)	
Median	2.64	2.45	3.65	2.89	
Min, Max	0.0, 9.1	0.0, 8.5	0.1, 8.1	0.0, 10.0	
C5D1 CFB					
n	29	51	34	68	
LS Mean (StdErr) [2]	-0.99 (0.328)	-1.39 (0.263)	-0.65 (0.373)	-1.12 (0.281)	
95% CI [2]	-1.64, -0.33	-1.92, -0.87	-1.39, 0.09	-1.68, -0.56	
Difference (95% CI) in CFB [2]		-0.41 (-1.13, 0.32)		-0.47 (-1.28, 0.34)	
p-value [3]		0.266		0.255	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	28	50	34	68	
Mean (StdDev)	2.97 (2.556)	2.72 (2.084)	3.54 (2.411)	2.92 (2.661)	
Median	2.64	2.29	2.85	2.04	
Min, Max	0.0, 8.9	0.0, 8.0	0.0, 8.3	0.0, 10.0	
C6D1 CFB					
n	28	50	34	68	
LS Mean (StdErr) [2]	-1.37 (0.339)	-1.69 (0.272)	-0.67 (0.379)	-1.33 (0.283)	
95% CI [2]	-2.04, -0.69	-2.23, -1.15	-1.43, 0.08	-1.89, -0.76	
Difference (95% CI) in CFB [2]		-0.33 (-1.08, 0.43)		-0.65 (-1.47, 0.17)	
p-value [3]		0.393		0.119	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	29	49	33	66	
Mean (StdDev)	3.20 (2.798)	2.56 (2.113)	3.45 (2.476)	2.98 (2.574)	
Median	2.07	1.86	3.45	2.73	
Min, Max	0.0, 8.9	0.0, 8.3	0.0, 7.9	0.0, 10.0	
C7D1 CFB					
n	29	49	33	66	
LS Mean (StdErr) [2]	-1.19 (0.365)	-1.76 (0.301)	-0.72 (0.362)	-1.27 (0.269)	
95% CI [2]	-1.92, -0.46	-2.36, -1.16	-1.44, 0.00	-1.80, -0.74	
Difference (95% CI) in CFB [2]		-0.57 (-1.38, 0.24)		-0.55 (-1.34, 0.23)	
Hedges'G (95% CI) in CFB		-0.27 (-0.75, 0.19)		-0.26 (-0.69, 0.16)	
p-value [3]		0.167		0.164	
					0.945

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	32	52	35	71	
Mean (StdDev)	1.52 (1.466)	1.76 (2.015)	1.55 (1.551)	1.36 (1.435)	
Median	1.08	1.15	1.15	1.00	
Min, Max	0.0, 6.1	0.0, 12.2	0.0, 7.2	0.0, 5.6	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	32	51	35	68	
Mean (StdDev)	1.41 (1.441)	1.41 (1.761)	1.14 (1.140)	0.98 (1.194)	
Median	0.64	0.93	0.71	0.50	
Min, Max	0.0, 4.9	0.0, 10.7	0.0, 3.8	0.0, 4.3	
C2D1 CFB					
n	32	51	35	68	
LS Mean (StdErr) [2]	-0.27 (0.180)	-0.48 (0.156)	-0.46 (0.156)	-0.45 (0.119)	
95% CI [2]	-0.63, 0.09	-0.79, -0.17	-0.77, -0.15	-0.69, -0.21	
Difference (95% CI) in CFB [2]		-0.21 (-0.61, 0.20)		0.01 (-0.33, 0.35)	
p-value [3]		0.311		0.968	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	32	50	35	67	
Mean (StdDev)	1.30 (1.268)	1.16 (1.270)	1.07 (1.086)	0.95 (1.183)	
Median	0.68	0.79	0.86	0.50	
Min, Max	0.0, 4.4	0.0, 5.6	0.0, 3.7	0.0, 5.8	
C3D1 CFB					
n	32	50	35	67	
LS Mean (StdErr) [2]	-0.48 (0.243)	-0.81 (0.211)	-0.51 (0.198)	-0.45 (0.152)	
95% CI [2]	-0.96, 0.01	-1.23, -0.39	-0.90, -0.11	-0.75, -0.15	
Difference (95% CI) in CFB [2]		-0.34 (-0.88, 0.21)		0.05 (-0.38, 0.49)	
p-value [3]		0.225		0.807	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	30	50	34	67	
Mean (StdDev)	1.17 (1.179)	1.28 (1.742)	1.18 (1.130)	0.87 (1.114)	
Median	0.73	0.67	0.89	0.36	
Min, Max	0.0, 4.3	0.0, 9.0	0.0, 4.8	0.0, 5.4	
C4D1 CFB					
n	30	50	34	67	
LS Mean (StdErr) [2]	-0.61 (0.222)	-0.64 (0.186)	-0.40 (0.206)	-0.50 (0.156)	
95% CI [2]	-1.05, -0.17	-1.01, -0.27	-0.81, 0.01	-0.81, -0.19	
Difference (95% CI) in CFB [2]		-0.03 (-0.52, 0.46)		-0.11 (-0.55, 0.34)	
p-value [3]		0.903		0.640	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	29	51	34	68	
Mean (StdDev)	1.16 (1.219)	1.31 (1.727)	1.16 (1.197)	0.83 (1.274)	
Median	0.57	0.73	0.86	0.40	
Min, Max	0.0, 4.0	0.0, 9.6	0.0, 4.8	0.0, 8.1	
C5D1 CFB					
n	29	51	34	68	
LS Mean (StdErr) [2]	-0.56 (0.227)	-0.59 (0.182)	-0.52 (0.252)	-0.65 (0.190)	
95% CI [2]	-1.01, -0.10	-0.95, -0.22	-1.03, -0.02	-1.02, -0.27	
Difference (95% CI) in CFB [2]		-0.03 (-0.53, 0.47)		-0.12 (-0.67, 0.42)	
p-value [3]		0.910		0.656	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	28	50	34	68	
Mean (StdDev)	0.94 (1.029)	1.25 (1.683)	1.22 (1.481)	0.77 (0.931)	
Median	0.50	0.55	0.68	0.43	
Min, Max	0.0, 3.4	0.0, 9.0	0.0, 6.5	0.0, 3.3	
C6D1 CFB					
n	28	50	34	68	
LS Mean (StdErr) [2]	-0.69 (0.219)	-0.69 (0.175)	-0.36 (0.200)	-0.56 (0.150)	
95% CI [2]	-1.13, -0.26	-1.04, -0.34	-0.76, 0.03	-0.86, -0.26	
Difference (95% CI) in CFB [2]		-0.00 (-0.49, 0.49)		-0.20 (-0.63, 0.24)	
p-value [3]		>0.999		0.369	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	29	49	33	66	
Mean (StdDev)	1.03 (1.240)	0.98 (1.256)	1.11 (1.299)	0.79 (0.991)	
Median	0.43	0.36	0.64	0.31	
Min, Max	0.0, 4.1	0.0, 4.8	0.0, 5.9	0.0, 4.0	
C7D1 CFB					
n	29	49	33	66	
LS Mean (StdErr) [2]	-0.51 (0.241)	-0.62 (0.199)	-0.48 (0.218)	-0.65 (0.162)	
95% CI [2]	-0.99, -0.03	-1.02, -0.22	-0.92, -0.05	-0.97, -0.33	
Difference (95% CI) in CFB [2]		-0.11 (-0.65, 0.42)		-0.17 (-0.64, 0.31)	
Hedges'G (95% CI) in CFB		-0.08 (-0.55, 0.38)		-0.13 (-0.56, 0.29)	
p-value [3]		0.676		0.483	
					0.889

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	32	52	35	71	
Mean (StdDev)	2.95 (2.669)	3.05 (2.518)	3.40 (2.614)	3.06 (2.368)	
Median	1.79	2.28	3.07	2.86	
Min, Max	0.0, 9.5	0.0, 9.5	0.0, 8.1	0.0, 9.4	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	32	51	35	68	
Mean (StdDev)	2.45 (2.551)	2.41 (2.164)	2.48 (2.317)	2.37 (2.518)	
Median	1.54	1.69	2.21	1.18	
Min, Max	0.0, 9.1	0.0, 8.0	0.0, 8.0	0.0, 8.9	
C2D1 CFB					
n	32	51	35	68	
LS Mean (StdErr) [2]	-0.66 (0.239)	-0.78 (0.207)	-0.65 (0.290)	-0.51 (0.222)	
95% CI [2]	-1.14, -0.19	-1.19, -0.36	-1.23, -0.08	-0.95, -0.07	
Difference (95% CI) in CFB [2]		-0.12 (-0.65, 0.42)		0.14 (-0.49, 0.78)	
p-value [3]		0.669		0.657	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	32	50	35	67	
Mean (StdDev)	2.43 (2.413)	2.11 (2.053)	2.26 (2.216)	2.22 (2.374)	
Median	1.68	1.39	1.50	1.50	
Min, Max	0.0, 8.7	0.0, 8.1	0.0, 8.0	0.0, 9.5	
C3D1 CFB					
n	32	50	35	67	
LS Mean (StdErr) [2]	-0.69 (0.313)	-1.08 (0.272)	-0.83 (0.351)	-0.58 (0.268)	
95% CI [2]	-1.31, -0.07	-1.62, -0.54	-1.52, -0.13	-1.11, -0.04	
Difference (95% CI) in CFB [2]		-0.39 (-1.10, 0.32)		0.25 (-0.52, 1.02)	
p-value [3]		0.276		0.521	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	30	50	34	67	
Mean (StdDev)	2.42 (2.461)	2.18 (2.235)	2.64 (2.300)	2.03 (2.386)	
Median	1.44	1.59	2.25	0.92	
Min, Max	0.0, 8.3	0.0, 8.9	0.0, 8.0	0.0, 8.3	
C4D1 CFB					
n	30	50	34	67	
LS Mean (StdErr) [2]	-0.75 (0.317)	-0.95 (0.265)	-0.56 (0.347)	-0.82 (0.263)	
95% CI [2]	-1.38, -0.12	-1.48, -0.43	-1.25, 0.13	-1.35, -0.30	
Difference (95% CI) in CFB [2]		-0.20 (-0.90, 0.50)		-0.27 (-1.02, 0.49)	
p-value [3]		0.565		0.487	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	29	51	34	68	
Mean (StdDev)	2.36 (2.391)	2.10 (2.213)	2.55 (2.406)	1.94 (2.293)	
Median	1.21	1.46	2.04	1.11	
Min, Max	0.0, 8.5	0.0, 8.5	0.0, 8.0	0.0, 9.0	
C5D1 CFB					
n	29	51	34	68	
LS Mean (StdErr) [2]	-0.79 (0.354)	-0.99 (0.284)	-0.76 (0.395)	-1.04 (0.298)	
95% CI [2]	-1.50, -0.09	-1.55, -0.42	-1.54, 0.03	-1.63, -0.45	
Difference (95% CI) in CFB [2]		-0.19 (-0.97, 0.59)		-0.28 (-1.14, 0.57)	
p-value [3]		0.625		0.514	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	28	50	34	68	
Mean (StdDev)	2.11 (2.480)	2.00 (2.169)	2.44 (2.303)	1.87 (2.290)	
Median	0.93	1.35	1.92	1.07	
Min, Max	0.0, 8.6	0.0, 8.6	0.0, 8.0	0.0, 8.9	
C6D1 CFB					
n	28	50	34	68	
LS Mean (StdErr) [2]	-0.86 (0.339)	-1.20 (0.272)	-0.64 (0.361)	-0.87 (0.270)	
95% CI [2]	-1.53, -0.18	-1.74, -0.66	-1.35, 0.08	-1.40, -0.33	
Difference (95% CI) in CFB [2]		-0.34 (-1.10, 0.41)		-0.23 (-1.01, 0.55)	
p-value [3]		0.366		0.564	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.3a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	29	49	33	66	
Mean (StdDev)	2.12 (2.643)	1.70 (2.147)	2.39 (2.353)	1.99 (2.348)	
Median	1.00	0.79	2.00	0.74	
Min, Max	0.0, 8.6	0.0, 8.4	0.0, 8.0	0.0, 8.7	
C7D1 CFB					
n	29	49	33	66	
LS Mean (StdErr) [2]	-0.79 (0.372)	-1.25 (0.307)	-0.81 (0.402)	-0.94 (0.298)	
95% CI [2]	-1.53, -0.05	-1.86, -0.64	-1.61, -0.01	-1.54, -0.35	
Difference (95% CI) in CFB [2]		-0.46 (-1.29, 0.37)		-0.13 (-1.00, 0.74)	
Hedges'G (95% CI) in CFB		-0.22 (-0.69, 0.24)		-0.05 (-0.48, 0.37)	
p-value [3]		0.272		0.769	
					0.564

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity

	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity						
	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

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[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity

	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

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[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity						
	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

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[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity

	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

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[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

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[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

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[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

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[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity

	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

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[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity						
	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

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[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity			
	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity						
	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

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[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity			
	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

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[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

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[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity						
	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

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[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity			
	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

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[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity						
	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

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[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity			
	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity						
	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

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[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

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[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity			
	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

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[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

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[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

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[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity

	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

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[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

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[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count			
	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity						
	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.4a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity			
	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	22	37	45	86	
Mean (StdDev)	3.61 (2.241)	3.76 (1.939)	6.49 (1.897)	6.41 (2.136)	
Median	3.92	3.29	6.69	6.58	
Min, Max	0.0, 8.2	0.0, 7.8	0.7, 10.0	0.0, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	22	35	45	84	
Mean (StdDev)	3.07 (2.095)	3.31 (1.846)	5.85 (2.296)	5.50 (2.565)	
Median	2.93	2.71	6.21	5.76	
Min, Max	0.0, 7.6	0.0, 7.2	0.5, 10.0	0.0, 10.0	
C2D1 CFB					
n	22	35	45	84	
LS Mean (StdErr) [2]	-0.72 (0.288)	-0.57 (0.212)	-0.60 (0.208)	-0.86 (0.167)	
95% CI [2]	-1.29, -0.14	-1.00, -0.14	-1.01, -0.19	-1.20, -0.53	
Difference (95% CI) in CFB [2]		0.15 (-0.48, 0.78)		-0.26 (-0.74, 0.22)	
p-value [3]		0.642		0.280	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	22	35	45	82	
Mean (StdDev)	3.05 (1.928)	2.95 (1.728)	5.71 (2.528)	5.21 (2.737)	
Median	2.98	2.64	6.29	5.13	
Min, Max	0.0, 7.4	0.0, 7.1	0.0, 10.0	0.0, 10.0	
C3D1 CFB					
n	22	35	45	82	
LS Mean (StdErr) [2]	-0.70 (0.356)	-0.91 (0.263)	-0.78 (0.243)	-1.20 (0.196)	
95% CI [2]	-1.42, 0.01	-1.44, -0.38	-1.26, -0.30	-1.58, -0.81	
Difference (95% CI) in CFB [2]		-0.21 (-0.98, 0.57)		-0.41 (-0.97, 0.15)	
p-value [3]		0.597		0.148	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	20	34	44	83	
Mean (StdDev)	2.92 (1.907)	2.93 (1.845)	5.73 (2.618)	5.17 (2.860)	
Median	2.85	2.61	6.54	5.43	
Min, Max	0.0, 7.2	0.0, 7.5	0.1, 9.8	0.0, 10.0	
C4D1 CFB					
n	20	34	44	83	
LS Mean (StdErr) [2]	-0.51 (0.467)	-0.69 (0.337)	-0.75 (0.286)	-1.19 (0.227)	
95% CI [2]	-1.45, 0.42	-1.37, -0.01	-1.31, -0.18	-1.64, -0.74	
Difference (95% CI) in CFB [2]		-0.18 (-1.20, 0.85)		-0.44 (-1.09, 0.21)	
p-value [3]		0.732		0.182	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	36	44	83	
Mean (StdDev)	2.64 (1.676)	2.83 (1.900)	5.80 (2.547)	4.87 (2.919)	
Median	3.00	2.55	6.33	4.79	
Min, Max	0.0, 6.1	0.0, 7.5	0.0, 9.8	0.0, 10.0	
C5D1 CFB					
n	19	36	44	83	
LS Mean (StdErr) [2]	-0.65 (0.447)	-0.74 (0.308)	-0.65 (0.314)	-1.45 (0.250)	
95% CI [2]	-1.54, 0.25	-1.36, -0.12	-1.27, -0.03	-1.95, -0.96	
Difference (95% CI) in CFB [2]		-0.09 (-1.07, 0.89)		-0.80 (-1.52, -0.09)	
p-value [3]		0.856		0.028	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	20	37	42	81	
Mean (StdDev)	3.27 (2.023)	2.70 (1.675)	5.54 (2.705)	4.74 (2.901)	
Median	3.55	2.31	6.12	5.21	
Min, Max	0.0, 6.8	0.0, 6.8	0.0, 9.6	0.0, 10.0	
C6D1 CFB					
n	20	37	42	81	
LS Mean (StdErr) [2]	0.01 (0.430)	-0.87 (0.300)	-0.83 (0.329)	-1.60 (0.259)	
95% CI [2]	-0.85, 0.88	-1.47, -0.27	-1.49, -0.18	-2.11, -1.08	
Difference (95% CI) in CFB [2]		-0.88 (-1.82, 0.06)		-0.76 (-1.52, -0.01)	
p-value [3]		0.066		0.047	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	19	36	43	79	
Mean (StdDev)	3.18 (2.026)	2.70 (1.678)	5.44 (2.708)	4.62 (3.018)	
Median	3.29	2.29	6.00	4.86	
Min, Max	0.0, 7.0	0.0, 7.4	0.0, 9.4	0.0, 10.0	
C7D1 CFB					
n	19	36	43	79	
LS Mean (StdErr) [2]	-0.11 (0.417)	-0.86 (0.287)	-0.99 (0.346)	-1.70 (0.280)	
95% CI [2]	-0.95, 0.73	-1.43, -0.28	-1.68, -0.30	-2.25, -1.14	
Difference (95% CI) in CFB [2]		-0.75 (-1.66, 0.17)		-0.71 (-1.50, 0.09)	
Hedges'G (95% CI) in CFB		-0.42 (-1.01, 0.14)		-0.29 (-0.67, 0.08)	
p-value [3]		0.107		0.080	
					0.982

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	22	37	45	86	
Mean (StdDev)	2.35 (1.813)	2.76 (1.464)	5.07 (2.165)	4.77 (2.173)	
Median	2.04	2.86	4.86	4.73	
Min, Max	0.0, 6.4	0.0, 6.1	0.0, 9.6	0.5, 9.8	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	22	35	45	84	
Mean (StdDev)	2.01 (1.532)	1.99 (1.421)	4.05 (2.159)	3.95 (2.157)	
Median	1.64	1.79	3.71	3.82	
Min, Max	0.0, 4.7	0.0, 6.0	0.2, 8.9	0.1, 9.4	
C2D1 CFB					
n	22	35	45	84	
LS Mean (StdErr) [2]	-0.28 (0.259)	-0.65 (0.191)	-1.01 (0.192)	-0.85 (0.155)	
95% CI [2]	-0.80, 0.24	-1.03, -0.26	-1.39, -0.63	-1.16, -0.55	
Difference (95% CI) in CFB [2]		-0.36 (-0.93, 0.20)		0.16 (-0.28, 0.60)	
p-value [3]		0.204		0.476	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	22	35	45	82	
Mean (StdDev)	1.92 (1.606)	1.92 (1.678)	3.79 (2.245)	3.38 (2.232)	
Median	1.53	1.29	3.69	3.18	
Min, Max	0.0, 5.1	0.0, 7.4	0.0, 8.4	0.0, 8.3	
C3D1 CFB					
n	22	35	45	82	
LS Mean (StdErr) [2]	-0.50 (0.346)	-0.79 (0.256)	-1.27 (0.240)	-1.41 (0.194)	
95% CI [2]	-1.20, 0.19	-1.30, -0.28	-1.75, -0.80	-1.79, -1.02	
Difference (95% CI) in CFB [2]		-0.29 (-1.04, 0.47)		-0.14 (-0.69, 0.42)	
p-value [3]		0.451		0.627	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	20	34	44	83	
Mean (StdDev)	1.78 (1.661)	1.52 (1.291)	3.78 (2.110)	3.15 (2.322)	
Median	1.14	1.23	3.77	3.07	
Min, Max	0.0, 5.6	0.0, 4.7	0.0, 7.9	0.0, 9.1	
C4D1 CFB					
n	20	34	44	83	
LS Mean (StdErr) [2]	-0.40 (0.352)	-0.97 (0.254)	-1.38 (0.299)	-1.72 (0.238)	
95% CI [2]	-1.11, 0.31	-1.49, -0.46	-1.97, -0.78	-2.19, -1.25	
Difference (95% CI) in CFB [2]		-0.57 (-1.35, 0.20)		-0.34 (-1.03, 0.34)	
p-value [3]		0.143		0.321	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	36	44	83	
Mean (StdDev)	2.01 (1.903)	1.62 (1.610)	3.78 (2.114)	2.99 (2.419)	
Median	1.57	1.19	3.86	2.54	
Min, Max	0.0, 5.6	0.0, 7.0	0.0, 8.1	0.0, 9.4	
C5D1 CFB					
n	19	36	44	83	
LS Mean (StdErr) [2]	-0.15 (0.443)	-0.91 (0.305)	-1.40 (0.320)	-1.90 (0.254)	
95% CI [2]	-1.04, 0.74	-1.52, -0.30	-2.03, -0.76	-2.40, -1.40	
Difference (95% CI) in CFB [2]		-0.76 (-1.73, 0.21)		-0.50 (-1.23, 0.23)	
p-value [3]		0.123		0.174	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	20	37	42	81	
Mean (StdDev)	1.69 (1.624)	1.65 (1.650)	3.19 (2.134)	2.78 (2.430)	
Median	1.14	1.36	3.07	2.57	
Min, Max	0.0, 5.1	0.0, 7.4	0.0, 7.1	0.0, 9.6	
C6D1 CFB					
n	20	37	42	81	
LS Mean (StdErr) [2]	-0.36 (0.358)	-1.03 (0.250)	-1.90 (0.349)	-2.03 (0.275)	
95% CI [2]	-1.07, 0.36	-1.53, -0.53	-2.59, -1.21	-2.58, -1.49	
Difference (95% CI) in CFB [2]		-0.67 (-1.45, 0.11)		-0.13 (-0.93, 0.67)	
p-value [3]		0.091		0.743	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	19	36	43	79	
Mean (StdDev)	1.44 (1.612)	1.61 (1.549)	3.53 (2.295)	2.85 (2.383)	
Median	1.00	1.14	3.23	2.73	
Min, Max	0.0, 5.4	0.0, 5.4	0.0, 8.3	0.0, 9.4	
C7D1 CFB					
n	19	36	43	79	
LS Mean (StdErr) [2]	-0.46 (0.349)	-0.97 (0.241)	-1.65 (0.340)	-2.01 (0.274)	
95% CI [2]	-1.16, 0.24	-1.45, -0.49	-2.32, -0.98	-2.55, -1.46	
Difference (95% CI) in CFB [2]		-0.51 (-1.28, 0.25)		-0.36 (-1.14, 0.42)	
Hedges'G (95% CI) in CFB		-0.34 (-0.93, 0.21)		-0.15 (-0.53, 0.22)	
p-value [3]		0.185		0.368	
					0.892

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	22	37	45	86	
Mean (StdDev)	1.59 (1.421)	1.67 (1.449)	4.49 (2.312)	3.87 (2.600)	
Median	1.15	1.50	4.86	3.81	
Min, Max	0.0, 4.1	0.0, 4.9	0.0, 8.9	0.0, 9.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	22	35	45	84	
Mean (StdDev)	1.53 (1.445)	1.31 (1.287)	3.71 (2.401)	3.32 (2.453)	
Median	0.96	0.92	3.69	3.25	
Min, Max	0.0, 4.1	0.0, 4.1	0.0, 8.3	0.0, 8.8	
C2D1 CFB					
n	22	35	45	84	
LS Mean (StdErr) [2]	0.13 (0.228)	-0.18 (0.168)	-0.81 (0.218)	-0.60 (0.175)	
95% CI [2]	-0.33, 0.58	-0.52, 0.15	-1.24, -0.38	-0.95, -0.26	
Difference (95% CI) in CFB [2]		-0.31 (-0.81, 0.19)		0.21 (-0.29, 0.71)	
p-value [3]		0.217		0.408	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	22	35	45	82	
Mean (StdDev)	1.35 (1.273)	1.25 (1.110)	3.29 (2.433)	2.93 (2.469)	
Median	1.00	1.31	2.77	2.68	
Min, Max	0.0, 3.6	0.0, 3.4	0.0, 7.7	0.0, 8.9	
C3D1 CFB					
n	22	35	45	82	
LS Mean (StdErr) [2]	-0.10 (0.248)	-0.26 (0.183)	-1.32 (0.266)	-1.09 (0.215)	
95% CI [2]	-0.59, 0.40	-0.63, 0.10	-1.84, -0.79	-1.52, -0.67	
Difference (95% CI) in CFB [2]		-0.17 (-0.71, 0.37)		0.22 (-0.39, 0.84)	
p-value [3]		0.536		0.474	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	20	34	44	83	
Mean (StdDev)	1.51 (1.449)	0.94 (0.935)	3.30 (2.308)	2.65 (2.438)	
Median	1.04	0.77	3.14	2.07	
Min, Max	0.0, 4.3	0.0, 2.9	0.0, 7.4	0.0, 9.2	
C4D1 CFB					
n	20	34	44	83	
LS Mean (StdErr) [2]	0.00 (0.315)	-0.53 (0.228)	-1.40 (0.299)	-1.44 (0.238)	
95% CI [2]	-0.63, 0.63	-0.99, -0.07	-1.99, -0.81	-1.91, -0.97	
Difference (95% CI) in CFB [2]		-0.53 (-1.22, 0.16)		-0.04 (-0.72, 0.64)	
p-value [3]		0.130		0.902	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	36	44	83	
Mean (StdDev)	1.58 (1.360)	1.09 (1.027)	3.32 (2.310)	2.57 (2.482)	
Median	1.71	0.89	3.09	2.00	
Min, Max	0.0, 4.1	0.0, 3.2	0.0, 8.5	0.0, 8.9	
C5D1 CFB					
n	19	36	44	83	
LS Mean (StdErr) [2]	0.15 (0.313)	-0.34 (0.216)	-1.42 (0.329)	-1.56 (0.262)	
95% CI [2]	-0.48, 0.77	-0.77, 0.09	-2.07, -0.77	-2.08, -1.04	
Difference (95% CI) in CFB [2]		-0.49 (-1.18, 0.20)		-0.14 (-0.89, 0.61)	
p-value [3]		0.159		0.707	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	20	37	42	81	
Mean (StdDev)	1.61 (1.567)	0.90 (0.972)	2.86 (2.224)	2.35 (2.424)	
Median	1.21	0.71	2.46	1.71	
Min, Max	0.0, 4.1	0.0, 3.3	0.0, 7.9	0.0, 9.9	
C6D1 CFB					
n	20	37	42	81	
LS Mean (StdErr) [2]	0.14 (0.335)	-0.70 (0.234)	-1.91 (0.329)	-1.73 (0.259)	
95% CI [2]	-0.53, 0.81	-1.17, -0.23	-2.56, -1.26	-2.24, -1.21	
Difference (95% CI) in CFB [2]		-0.84 (-1.57, -0.11)		0.18 (-0.57, 0.93)	
p-value [3]		0.025		0.634	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	19	36	43	79	
Mean (StdDev)	1.38 (1.509)	1.04 (1.036)	3.08 (2.363)	2.35 (2.436)	
Median	0.79	0.76	3.21	1.57	
Min, Max	0.0, 4.6	0.0, 3.1	0.0, 7.7	0.0, 9.5	
C7D1 CFB					
n	19	36	43	79	
LS Mean (StdErr) [2]	0.12 (0.332)	-0.43 (0.229)	-1.74 (0.359)	-1.78 (0.290)	
95% CI [2]	-0.55, 0.79	-0.89, 0.03	-2.45, -1.03	-2.35, -1.20	
Difference (95% CI) in CFB [2]		-0.55 (-1.28, 0.18)		-0.04 (-0.86, 0.79)	
Hedges'G (95% CI) in CFB		-0.39 (-0.98, 0.17)		-0.01 (-0.39, 0.36)	
p-value [3]		0.135		0.928	
					0.570

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	22	37	45	86	
Mean (StdDev)	4.59 (3.402)	4.04 (2.452)	6.74 (2.564)	6.19 (3.017)	
Median	4.14	3.93	7.07	6.64	
Min, Max	0.0, 10.0	0.0, 8.2	0.0, 10.0	0.0, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	22	35	45	84	
Mean (StdDev)	4.39 (3.218)	3.46 (2.428)	6.23 (2.487)	5.14 (2.751)	
Median	3.68	3.21	6.57	5.18	
Min, Max	0.0, 10.0	0.0, 7.5	0.0, 10.0	0.0, 10.0	
C2D1 CFB					
n	22	35	45	84	
LS Mean (StdErr) [2]	-0.24 (0.189)	-0.62 (0.140)	-0.51 (0.221)	-1.07 (0.178)	
95% CI [2]	-0.62, 0.14	-0.90, -0.34	-0.95, -0.08	-1.42, -0.72	
Difference (95% CI) in CFB [2]		-0.38 (-0.80, 0.03)		-0.55 (-1.06, -0.05)	
p-value [3]		0.068		0.033	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	22	35	45	82	
Mean (StdDev)	4.42 (3.300)	3.29 (2.412)	6.15 (2.555)	4.61 (2.598)	
Median	4.11	3.21	5.86	4.25	
Min, Max	0.0, 10.0	0.0, 7.0	0.0, 10.0	0.0, 9.8	
C3D1 CFB					
n	22	35	45	82	
LS Mean (StdErr) [2]	-0.21 (0.332)	-0.78 (0.245)	-0.54 (0.256)	-1.59 (0.207)	
95% CI [2]	-0.87, 0.46	-1.27, -0.29	-1.05, -0.04	-2.00, -1.18	
Difference (95% CI) in CFB [2]		-0.57 (-1.30, 0.15)		-1.05 (-1.64, -0.46)	
p-value [3]		0.118		<0.001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	20	34	44	83	
Mean (StdDev)	4.20 (3.284)	3.13 (2.349)	6.08 (2.576)	4.34 (2.624)	
Median	3.56	2.54	6.21	4.00	
Min, Max	0.0, 10.0	0.0, 7.1	0.0, 10.0	0.0, 9.4	
C4D1 CFB					
n	20	34	44	83	
LS Mean (StdErr) [2]	0.05 (0.243)	-0.88 (0.176)	-0.52 (0.289)	-1.71 (0.230)	
95% CI [2]	-0.44, 0.54	-1.24, -0.53	-1.10, 0.05	-2.16, -1.25	
Difference (95% CI) in CFB [2]		-0.93 (-1.47, -0.40)		-1.18 (-1.84, -0.52)	
p-value [3]		<0.001		<0.001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	36	44	83	
Mean (StdDev)	4.24 (3.213)	2.90 (2.141)	5.90 (2.657)	4.13 (2.663)	
Median	4.43	2.62	5.43	3.71	
Min, Max	0.0, 10.0	0.0, 7.0	0.0, 10.0	0.0, 9.9	
C5D1 CFB					
n	19	36	44	83	
LS Mean (StdErr) [2]	0.02 (0.312)	-1.15 (0.215)	-0.76 (0.307)	-1.97 (0.244)	
95% CI [2]	-0.61, 0.64	-1.58, -0.72	-1.36, -0.15	-2.45, -1.48	
Difference (95% CI) in CFB [2]		-1.17 (-1.85, -0.48)		-1.21 (-1.91, -0.51)	
p-value [3]		0.001		<0.001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	20	37	42	81	
Mean (StdDev)	4.43 (3.115)	2.74 (2.067)	5.98 (2.715)	3.99 (2.703)	
Median	4.08	2.00	5.43	3.44	
Min, Max	0.0, 10.0	0.0, 6.9	0.0, 10.0	0.0, 10.0	
C6D1 CFB					
n	20	37	42	81	
LS Mean (StdErr) [2]	-0.09 (0.326)	-1.28 (0.227)	-0.51 (0.369)	-1.98 (0.290)	
95% CI [2]	-0.75, 0.56	-1.74, -0.83	-1.24, 0.22	-2.55, -1.40	
Difference (95% CI) in CFB [2]		-1.19 (-1.90, -0.48)		-1.46 (-2.30, -0.62)	
p-value [3]		0.001		<0.001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	19	36	43	79	
Mean (StdDev)	4.69 (2.872)	2.74 (2.141)	5.87 (2.796)	3.94 (2.804)	
Median	4.14	2.07	5.46	3.36	
Min, Max	0.0, 10.0	0.0, 6.7	0.0, 10.0	0.0, 10.0	
C7D1 CFB					
n	19	36	43	79	
LS Mean (StdErr) [2]	-0.12 (0.330)	-1.33 (0.228)	-0.68 (0.377)	-2.10 (0.304)	
95% CI [2]	-0.78, 0.54	-1.79, -0.88	-1.43, 0.07	-2.70, -1.50	
Difference (95% CI) in CFB [2]		-1.21 (-1.94, -0.49)		-1.42 (-2.28, -0.56)	
Hedges'G (95% CI) in CFB		-0.86 (-1.49, -0.30)		-0.54 (-0.93, -0.17)	
p-value [3]		0.001		0.001	
					0.861

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	22	37	45	86	
Mean (StdDev)	4.15 (2.620)	3.70 (2.284)	6.86 (2.176)	6.21 (2.484)	
Median	4.20	3.93	7.00	6.37	
Min, Max	0.0, 9.0	0.0, 7.3	1.2, 10.0	0.0, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	22	35	45	84	
Mean (StdDev)	3.53 (2.691)	2.87 (2.231)	6.14 (2.344)	4.99 (2.143)	
Median	2.71	2.64	6.29	4.89	
Min, Max	0.0, 8.9	0.0, 7.3	1.1, 10.0	0.1, 9.9	
C2D1 CFB					
n	22	35	45	84	
LS Mean (StdErr) [2]	-0.96 (0.299)	-1.01 (0.221)	-0.76 (0.275)	-1.30 (0.222)	
95% CI [2]	-1.56, -0.36	-1.46, -0.57	-1.31, -0.22	-1.74, -0.86	
Difference (95% CI) in CFB [2]		-0.05 (-0.71, 0.60)		-0.53 (-1.17, 0.10)	
p-value [3]		0.872		0.098	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	22	35	45	82	
Mean (StdDev)	3.45 (2.601)	2.61 (2.104)	5.76 (2.493)	4.13 (2.444)	
Median	3.07	2.15	5.71	3.84	
Min, Max	0.0, 9.0	0.0, 6.7	0.9, 10.0	0.0, 9.7	
C3D1 CFB					
n	22	35	45	82	
LS Mean (StdErr) [2]	-1.02 (0.402)	-1.25 (0.297)	-1.07 (0.329)	-2.07 (0.266)	
95% CI [2]	-1.82, -0.21	-1.85, -0.66	-1.72, -0.41	-2.60, -1.55	
Difference (95% CI) in CFB [2]		-0.24 (-1.11, 0.64)		-1.01 (-1.77, -0.25)	
p-value [3]		0.593		0.010	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	20	34	44	83	
Mean (StdDev)	3.07 (2.582)	2.31 (1.971)	5.74 (2.503)	3.91 (2.613)	
Median	2.43	2.11	5.74	3.57	
Min, Max	0.0, 7.9	0.0, 6.7	0.0, 10.0	0.0, 10.0	
C4D1 CFB					
n	20	34	44	83	
LS Mean (StdErr) [2]	-1.23 (0.369)	-1.55 (0.266)	-1.13 (0.409)	-2.28 (0.325)	
95% CI [2]	-1.97, -0.49	-2.08, -1.01	-1.94, -0.32	-2.93, -1.64	
Difference (95% CI) in CFB [2]		-0.31 (-1.12, 0.50)		-1.16 (-2.09, -0.22)	
p-value [3]		0.440		0.015	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	36	44	83	
Mean (StdDev)	3.64 (2.363)	2.29 (1.831)	5.62 (2.572)	3.57 (2.679)	
Median	3.50	2.07	5.52	3.21	
Min, Max	0.0, 7.2	0.0, 6.7	0.1, 10.0	0.0, 10.0	
C5D1 CFB					
n	19	36	44	83	
LS Mean (StdErr) [2]	-0.77 (0.404)	-1.55 (0.279)	-1.25 (0.421)	-2.61 (0.335)	
95% CI [2]	-1.58, 0.04	-2.11, -0.99	-2.08, -0.41	-3.27, -1.95	
Difference (95% CI) in CFB [2]		-0.78 (-1.66, 0.11)		-1.36 (-2.32, -0.41)	
p-value [3]		0.085		0.006	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	20	37	42	81	
Mean (StdDev)	3.46 (2.103)	2.19 (1.762)	5.64 (2.646)	3.53 (2.736)	
Median	3.54	2.07	5.71	3.00	
Min, Max	0.0, 7.5	0.0, 6.4	0.0, 10.0	0.0, 10.0	
C6D1 CFB					
n	20	37	42	81	
LS Mean (StdErr) [2]	-1.03 (0.451)	-1.63 (0.315)	-1.28 (0.430)	-2.80 (0.338)	
95% CI [2]	-1.94, -0.13	-2.26, -1.00	-2.13, -0.43	-3.47, -2.13	
Difference (95% CI) in CFB [2]		-0.60 (-1.58, 0.39)		-1.52 (-2.50, -0.54)	
p-value [3]		0.228		0.003	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	19	36	43	79	
Mean (StdDev)	3.66 (1.975)	2.29 (1.834)	5.66 (2.557)	3.39 (2.699)	
Median	3.00	2.00	5.86	3.27	
Min, Max	1.1, 7.0	0.0, 7.5	0.0, 10.0	0.0, 10.0	
C7D1 CFB					
n	19	36	43	79	
LS Mean (StdErr) [2]	-1.10 (0.473)	-1.57 (0.326)	-1.27 (0.446)	-2.93 (0.360)	
95% CI [2]	-2.05, -0.15	-2.23, -0.92	-2.15, -0.39	-3.65, -2.22	
Difference (95% CI) in CFB [2]		-0.47 (-1.51, 0.57)		-1.66 (-2.69, -0.64)	
Hedges'G (95% CI) in CFB		-0.23 (-0.81, 0.33)		-0.53 (-0.92, -0.16)	
p-value [3]		0.367		0.002	
					0.184

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	22	37	45	86	
Mean (StdDev)	4.62 (2.395)	3.45 (2.400)	6.58 (2.393)	6.23 (1.881)	
Median	4.85	3.33	6.42	6.04	
Min, Max	0.0, 9.0	0.0, 7.6	0.0, 10.0	2.9, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	22	35	45	84	
Mean (StdDev)	3.99 (2.471)	3.06 (2.404)	6.07 (2.457)	5.36 (2.159)	
Median	3.39	2.92	5.73	5.36	
Min, Max	0.0, 8.9	0.0, 7.4	0.0, 10.0	0.5, 10.0	
C2D1 CFB					
n	22	35	45	84	
LS Mean (StdErr) [2]	-0.88 (0.300)	-0.49 (0.222)	-0.53 (0.248)	-0.92 (0.200)	
95% CI [2]	-1.48, -0.27	-0.94, -0.05	-1.02, -0.04	-1.31, -0.52	
Difference (95% CI) in CFB [2]		0.38 (-0.27, 1.04)		-0.39 (-0.96, 0.19)	
p-value [3]		0.249		0.184	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	22	35	45	82	
Mean (StdDev)	3.83 (2.481)	2.75 (2.195)	5.87 (2.718)	4.74 (2.401)	
Median	3.70	2.57	5.50	4.69	
Min, Max	0.0, 8.5	0.0, 7.4	0.0, 10.0	0.0, 10.0	
C3D1 CFB					
n	22	35	45	82	
LS Mean (StdErr) [2]	-1.13 (0.387)	-0.86 (0.286)	-0.66 (0.292)	-1.50 (0.237)	
95% CI [2]	-1.91, -0.35	-1.44, -0.29	-1.24, -0.08	-1.96, -1.03	
Difference (95% CI) in CFB [2]		0.27 (-0.58, 1.11)		-0.84 (-1.51, -0.16)	
p-value [3]		0.528		0.015	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	20	34	44	83	
Mean (StdDev)	3.58 (2.415)	2.49 (1.933)	5.89 (2.761)	4.51 (2.515)	
Median	3.04	2.19	5.86	4.67	
Min, Max	0.0, 8.0	0.0, 6.9	0.1, 10.0	0.0, 10.0	
C4D1 CFB					
n	20	34	44	83	
LS Mean (StdErr) [2]	-1.26 (0.481)	-1.07 (0.348)	-0.73 (0.330)	-1.80 (0.262)	
95% CI [2]	-2.23, -0.29	-1.76, -0.37	-1.38, -0.07	-2.32, -1.28	
Difference (95% CI) in CFB [2]		0.19 (-0.86, 1.25)		-1.08 (-1.83, -0.33)	
p-value [3]		0.714		0.005	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	36	44	83	
Mean (StdDev)	3.71 (2.490)	2.34 (2.012)	5.84 (2.769)	4.34 (2.519)	
Median	4.00	2.00	5.78	4.38	
Min, Max	0.0, 8.0	0.0, 6.4	0.0, 10.0	0.0, 9.8	
C5D1 CFB					
n	19	36	44	83	
LS Mean (StdErr) [2]	-1.07 (0.488)	-1.23 (0.337)	-0.83 (0.377)	-2.04 (0.299)	
95% CI [2]	-2.05, -0.09	-1.91, -0.56	-1.58, -0.09	-2.63, -1.45	
Difference (95% CI) in CFB [2]		-0.17 (-1.24, 0.91)		-1.21 (-2.07, -0.35)	
p-value [3]		0.757		0.006	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	20	37	42	81	
Mean (StdDev)	3.85 (2.378)	2.18 (1.948)	5.62 (2.951)	4.24 (2.585)	
Median	3.89	1.50	5.58	4.17	
Min, Max	0.0, 8.0	0.0, 6.5	0.1, 10.0	0.0, 10.0	
C6D1 CFB					
n	20	37	42	81	
LS Mean (StdErr) [2]	-1.18 (0.507)	-1.37 (0.353)	-1.01 (0.396)	-2.21 (0.312)	
95% CI [2]	-2.20, -0.16	-2.08, -0.66	-1.80, -0.23	-2.82, -1.59	
Difference (95% CI) in CFB [2]		-0.19 (-1.29, 0.92)		-1.19 (-2.10, -0.29)	
p-value [3]		0.735		0.010	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	19	36	43	79	
Mean (StdDev)	4.00 (2.138)	2.13 (2.020)	5.61 (2.974)	3.92 (2.577)	
Median	4.00	1.36	5.93	3.64	
Min, Max	0.0, 8.0	0.0, 7.2	0.0, 10.0	0.0, 10.0	
C7D1 CFB					
n	19	36	43	79	
LS Mean (StdErr) [2]	-1.14 (0.589)	-1.33 (0.406)	-1.00 (0.393)	-2.43 (0.317)	
95% CI [2]	-2.32, 0.05	-2.14, -0.51	-1.78, -0.22	-3.06, -1.80	
Difference (95% CI) in CFB [2]		-0.19 (-1.49, 1.10)		-1.43 (-2.33, -0.53)	
Hedges'G (95% CI) in CFB		-0.08 (-0.65, 0.49)		-0.52 (-0.91, -0.15)	
p-value [3]		0.765		0.002	
					0.123

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	22	37	45	86	
Mean (StdDev)	5.43 (2.007)	5.28 (1.772)	7.45 (1.652)	7.66 (1.619)	
Median	5.56	5.43	7.21	7.70	
Min, Max	0.0, 8.0	0.1, 8.8	3.8, 10.0	2.8, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	22	35	45	84	
Mean (StdDev)	5.18 (1.643)	4.68 (1.727)	6.96 (1.804)	6.92 (2.044)	
Median	4.89	5.07	6.91	7.00	
Min, Max	2.3, 8.3	0.1, 7.2	2.8, 10.0	1.0, 10.0	
C2D1 CFB					
n	22	35	45	84	
LS Mean (StdErr) [2]	-0.35 (0.283)	-0.68 (0.209)	-0.52 (0.202)	-0.77 (0.163)	
95% CI [2]	-0.92, 0.22	-1.10, -0.26	-0.92, -0.12	-1.09, -0.45	
Difference (95% CI) in CFB [2]		-0.33 (-0.95, 0.29)		-0.25 (-0.71, 0.22)	
p-value [3]		0.288		0.298	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	22	35	45	82	
Mean (StdDev)	4.93 (2.007)	4.24 (1.707)	6.57 (2.202)	6.49 (2.204)	
Median	4.57	4.29	6.29	6.56	
Min, Max	0.3, 8.1	0.9, 7.8	0.3, 10.0	0.2, 10.0	
C3D1 CFB					
n	22	35	45	82	
LS Mean (StdErr) [2]	-0.66 (0.402)	-1.16 (0.297)	-0.88 (0.252)	-1.15 (0.204)	
95% CI [2]	-1.46, 0.15	-1.75, -0.56	-1.38, -0.38	-1.56, -0.75	
Difference (95% CI) in CFB [2]		-0.50 (-1.38, 0.38)		-0.27 (-0.86, 0.31)	
p-value [3]		0.258		0.352	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	20	34	44	83	
Mean (StdDev)	4.77 (1.998)	3.98 (1.804)	6.31 (2.409)	6.15 (2.446)	
Median	4.49	3.82	6.26	6.29	
Min, Max	1.3, 7.9	0.9, 7.7	0.2, 10.0	0.0, 10.0	
C4D1 CFB					
n	20	34	44	83	
LS Mean (StdErr) [2]	-0.45 (0.482)	-1.25 (0.348)	-1.25 (0.314)	-1.61 (0.249)	
95% CI [2]	-1.42, 0.52	-1.95, -0.55	-1.87, -0.63	-2.11, -1.12	
Difference (95% CI) in CFB [2]		-0.80 (-1.86, 0.26)		-0.36 (-1.08, 0.35)	
p-value [3]		0.135		0.317	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	36	44	83	
Mean (StdDev)	4.27 (1.831)	4.08 (1.921)	6.33 (2.396)	6.08 (2.415)	
Median	4.14	3.93	6.00	6.14	
Min, Max	1.2, 7.4	0.3, 8.0	0.6, 10.0	0.0, 10.0	
C5D1 CFB					
n	19	36	44	83	
LS Mean (StdErr) [2]	-0.71 (0.470)	-1.09 (0.324)	-1.20 (0.331)	-1.65 (0.263)	
95% CI [2]	-1.65, 0.24	-1.74, -0.44	-1.85, -0.54	-2.17, -1.13	
Difference (95% CI) in CFB [2]		-0.38 (-1.42, 0.65)		-0.45 (-1.21, 0.30)	
p-value [3]		0.458		0.235	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	20	37	42	81	
Mean (StdDev)	4.97 (1.895)	3.71 (2.060)	6.19 (2.512)	5.88 (2.718)	
Median	4.57	3.43	6.11	6.07	
Min, Max	2.0, 8.4	0.0, 8.3	0.4, 10.0	0.0, 10.0	
C6D1 CFB					
n	20	37	42	81	
LS Mean (StdErr) [2]	-0.19 (0.486)	-1.54 (0.339)	-1.28 (0.362)	-1.79 (0.285)	
95% CI [2]	-1.16, 0.78	-2.22, -0.86	-1.99, -0.56	-2.36, -1.23	
Difference (95% CI) in CFB [2]		-1.35 (-2.41, -0.29)		-0.52 (-1.35, 0.31)	
p-value [3]		0.013		0.218	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	19	36	43	79	
Mean (StdDev)	4.67 (1.979)	3.98 (2.043)	6.24 (2.560)	5.53 (2.737)	
Median	4.64	3.61	6.00	5.83	
Min, Max	0.2, 7.7	0.3, 8.4	0.4, 10.0	0.0, 10.0	
C7D1 CFB					
n	19	36	43	79	
LS Mean (StdErr) [2]	-0.65 (0.514)	-1.38 (0.355)	-1.22 (0.360)	-2.11 (0.290)	
95% CI [2]	-1.68, 0.38	-2.09, -0.67	-1.93, -0.51	-2.68, -1.53	
Difference (95% CI) in CFB [2]		-0.73 (-1.86, 0.40)		-0.89 (-1.71, -0.06)	
Hedges'G (95% CI) in CFB		-0.33 (-0.92, 0.23)		-0.35 (-0.74, 0.02)	
p-value [3]		0.200		0.036	
					0.847

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	22	37	45	86	
Mean (StdDev)	2.37 (1.663)	1.55 (1.497)	4.37 (2.982)	5.00 (2.612)	
Median	2.29	0.83	4.00	4.96	
Min, Max	0.0, 6.3	0.0, 5.0	0.0, 9.3	0.0, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	22	35	45	84	
Mean (StdDev)	1.84 (1.696)	1.44 (1.521)	3.88 (2.826)	4.17 (2.633)	
Median	1.78	0.92	3.50	3.93	
Min, Max	0.0, 6.3	0.0, 5.4	0.0, 8.7	0.0, 10.0	
C2D1 CFB					
n	22	35	45	84	
LS Mean (StdErr) [2]	-0.49 (0.288)	-0.14 (0.213)	-0.57 (0.236)	-0.93 (0.190)	
95% CI [2]	-1.06, 0.09	-0.57, 0.28	-1.04, -0.11	-1.31, -0.55	
Difference (95% CI) in CFB [2]		0.34 (-0.29, 0.97)		-0.36 (-0.90, 0.19)	
p-value [3]		0.281		0.196	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	22	35	45	82	
Mean (StdDev)	1.74 (1.813)	1.23 (1.321)	3.45 (2.722)	3.71 (2.804)	
Median	1.21	0.64	2.54	3.48	
Min, Max	0.0, 6.5	0.0, 5.1	0.0, 8.1	0.0, 10.0	
C3D1 CFB					
n	22	35	45	82	
LS Mean (StdErr) [2]	-0.61 (0.312)	-0.36 (0.230)	-0.99 (0.281)	-1.40 (0.227)	
95% CI [2]	-1.24, 0.01	-0.82, 0.10	-1.54, -0.43	-1.85, -0.95	
Difference (95% CI) in CFB [2]		0.25 (-0.43, 0.93)		-0.41 (-1.06, 0.24)	
p-value [3]		0.461		0.215	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	20	34	44	83	
Mean (StdDev)	2.23 (1.955)	1.18 (1.290)	3.43 (2.853)	3.60 (2.878)	
Median	2.04	0.86	2.93	3.21	
Min, Max	0.0, 6.7	0.0, 5.2	0.0, 9.9	0.0, 10.0	
C4D1 CFB					
n	20	34	44	83	
LS Mean (StdErr) [2]	0.08 (0.324)	-0.33 (0.234)	-1.13 (0.347)	-1.59 (0.276)	
95% CI [2]	-0.57, 0.73	-0.80, 0.14	-1.82, -0.44	-2.14, -1.05	
Difference (95% CI) in CFB [2]		-0.41 (-1.12, 0.30)		-0.46 (-1.25, 0.33)	
p-value [3]		0.255		0.249	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	36	44	83	
Mean (StdDev)	1.96 (1.941)	1.26 (1.470)	3.54 (2.730)	3.36 (2.815)	
Median	1.36	0.63	2.96	2.46	
Min, Max	0.0, 6.8	0.0, 5.4	0.0, 9.6	0.0, 10.0	
C5D1 CFB					
n	19	36	44	83	
LS Mean (StdErr) [2]	-0.15 (0.341)	-0.20 (0.235)	-0.99 (0.336)	-1.79 (0.267)	
95% CI [2]	-0.83, 0.53	-0.67, 0.27	-1.66, -0.33	-2.32, -1.27	
Difference (95% CI) in CFB [2]		-0.05 (-0.80, 0.70)		-0.80 (-1.57, -0.04)	
p-value [3]		0.893		0.040	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	20	37	42	81	
Mean (StdDev)	1.85 (1.850)	1.16 (1.366)	3.33 (2.781)	3.05 (2.766)	
Median	1.22	0.36	2.14	2.62	
Min, Max	0.0, 6.0	0.0, 4.8	0.0, 8.6	0.0, 10.0	
C6D1 CFB					
n	20	37	42	81	
LS Mean (StdErr) [2]	-0.27 (0.351)	-0.30 (0.244)	-1.29 (0.366)	-2.17 (0.288)	
95% CI [2]	-0.98, 0.43	-0.79, 0.20	-2.01, -0.56	-2.74, -1.60	
Difference (95% CI) in CFB [2]		-0.02 (-0.79, 0.74)		-0.89 (-1.72, -0.05)	
p-value [3]		0.952		0.038	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	19	36	43	79	
Mean (StdDev)	1.88 (1.803)	1.13 (1.276)	3.30 (2.870)	3.08 (2.792)	
Median	1.36	0.60	2.15	2.50	
Min, Max	0.0, 5.6	0.0, 4.5	0.0, 10.0	0.0, 10.0	
C7D1 CFB					
n	19	36	43	79	
LS Mean (StdErr) [2]	-0.17 (0.396)	-0.35 (0.273)	-1.38 (0.374)	-2.11 (0.302)	
95% CI [2]	-0.96, 0.63	-0.89, 0.20	-2.12, -0.64	-2.71, -1.51	
Difference (95% CI) in CFB [2]		-0.18 (-1.05, 0.69)		-0.73 (-1.59, 0.13)	
Hedges'G (95% CI) in CFB		-0.11 (-0.68, 0.46)		-0.28 (-0.66, 0.09)	
p-value [3]		0.679		0.095	
					0.360

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	22	37	45	86	
Mean (StdDev)	3.50 (2.019)	4.00 (1.738)	6.07 (2.566)	6.38 (2.345)	
Median	3.43	3.75	5.93	6.43	
Min, Max	0.0, 6.9	0.0, 7.1	0.0, 10.0	0.0, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	22	35	45	84	
Mean (StdDev)	3.02 (1.726)	3.48 (1.819)	5.51 (2.632)	5.58 (2.755)	
Median	2.86	3.23	5.57	5.82	
Min, Max	0.0, 6.5	0.0, 7.0	0.0, 10.0	0.0, 10.0	
C2D1 CFB					
n	22	35	45	84	
LS Mean (StdErr) [2]	-0.54 (0.221)	-0.60 (0.163)	-0.55 (0.195)	-0.78 (0.157)	
95% CI [2]	-0.98, -0.10	-0.93, -0.28	-0.94, -0.17	-1.09, -0.47	
Difference (95% CI) in CFB [2]		-0.06 (-0.55, 0.42)		-0.23 (-0.68, 0.22)	
p-value [3]		0.798		0.311	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	22	35	45	82	
Mean (StdDev)	3.08 (1.961)	3.03 (1.810)	5.18 (2.730)	5.30 (2.827)	
Median	3.07	3.00	5.07	5.39	
Min, Max	0.0, 6.8	0.0, 7.0	0.0, 10.0	0.0, 10.0	
C3D1 CFB					
n	22	35	45	82	
LS Mean (StdErr) [2]	-0.55 (0.307)	-1.09 (0.227)	-0.83 (0.234)	-1.06 (0.190)	
95% CI [2]	-1.17, 0.06	-1.55, -0.64	-1.30, -0.37	-1.44, -0.69	
Difference (95% CI) in CFB [2]		-0.54 (-1.21, 0.13)		-0.23 (-0.77, 0.31)	
p-value [3]		0.111		0.403	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	20	34	44	83	
Mean (StdDev)	2.76 (1.898)	2.93 (1.971)	4.99 (2.808)	5.02 (2.956)	
Median	2.71	2.80	4.79	5.17	
Min, Max	0.0, 6.9	0.0, 7.0	0.0, 10.0	0.0, 10.0	
C4D1 CFB					
n	20	34	44	83	
LS Mean (StdErr) [2]	-0.68 (0.410)	-1.08 (0.296)	-1.05 (0.288)	-1.35 (0.229)	
95% CI [2]	-1.50, 0.14	-1.67, -0.48	-1.62, -0.48	-1.81, -0.90	
Difference (95% CI) in CFB [2]		-0.40 (-1.30, 0.50)		-0.30 (-0.96, 0.35)	
p-value [3]		0.378		0.364	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	36	44	83	
Mean (StdDev)	2.33 (1.745)	3.05 (2.072)	4.84 (2.806)	4.93 (3.004)	
Median	2.50	2.82	4.44	5.00	
Min, Max	0.0, 5.2	0.0, 7.0	0.0, 10.0	0.0, 10.0	
C5D1 CFB					
n	19	36	44	83	
LS Mean (StdErr) [2]	-0.88 (0.431)	-0.92 (0.297)	-1.15 (0.317)	-1.37 (0.252)	
95% CI [2]	-1.74, -0.01	-1.51, -0.32	-1.77, -0.52	-1.86, -0.87	
Difference (95% CI) in CFB [2]		-0.04 (-0.99, 0.91)		-0.22 (-0.94, 0.50)	
p-value [3]		0.934		0.549	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	20	37	42	81	
Mean (StdDev)	3.16 (2.157)	2.98 (2.063)	4.65 (2.843)	4.73 (3.122)	
Median	3.21	2.92	4.48	5.07	
Min, Max	0.0, 7.9	0.0, 7.1	0.0, 10.0	0.0, 10.0	
C6D1 CFB					
n	20	37	42	81	
LS Mean (StdErr) [2]	-0.20 (0.387)	-1.00 (0.270)	-1.32 (0.323)	-1.65 (0.254)	
95% CI [2]	-0.98, 0.58	-1.54, -0.46	-1.96, -0.69	-2.16, -1.15	
Difference (95% CI) in CFB [2]		-0.80 (-1.65, 0.05)		-0.33 (-1.07, 0.41)	
p-value [3]		0.063		0.380	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	19	36	43	79	
Mean (StdDev)	2.94 (2.064)	3.00 (2.141)	4.74 (2.962)	4.63 (3.164)	
Median	2.91	3.00	4.36	4.79	
Min, Max	0.0, 7.9	0.0, 7.0	0.0, 10.0	0.0, 10.0	
C7D1 CFB					
n	19	36	43	79	
LS Mean (StdErr) [2]	-0.41 (0.430)	-1.05 (0.297)	-1.26 (0.330)	-1.71 (0.266)	
95% CI [2]	-1.27, 0.45	-1.65, -0.46	-1.91, -0.60	-2.24, -1.19	
Difference (95% CI) in CFB [2]		-0.64 (-1.59, 0.30)		-0.46 (-1.21, 0.30)	
Hedges'G (95% CI) in CFB		-0.35 (-0.94, 0.21)		-0.20 (-0.58, 0.17)	
p-value [3]		0.177		0.232	
					0.758

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	22	37	45	86	
Mean (StdDev)	2.25 (1.942)	2.91 (1.983)	5.23 (2.491)	4.93 (2.425)	
Median	1.89	2.79	5.58	4.87	
Min, Max	0.0, 6.9	0.0, 7.2	0.3, 9.9	0.0, 9.9	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	22	35	45	84	
Mean (StdDev)	2.23 (2.006)	2.44 (1.898)	4.75 (2.451)	4.26 (2.420)	
Median	2.00	2.21	4.64	3.93	
Min, Max	0.0, 7.0	0.0, 7.5	0.5, 9.1	0.0, 10.0	
C2D1 CFB					
n	22	35	45	84	
LS Mean (StdErr) [2]	-0.08 (0.257)	-0.46 (0.190)	-0.55 (0.216)	-0.77 (0.174)	
95% CI [2]	-0.59, 0.44	-0.84, -0.08	-0.97, -0.12	-1.11, -0.42	
Difference (95% CI) in CFB [2]		-0.39 (-0.95, 0.18)		-0.22 (-0.72, 0.28)	
p-value [3]		0.175		0.380	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	22	35	45	82	
Mean (StdDev)	1.95 (1.906)	2.31 (1.753)	4.34 (2.493)	3.80 (2.495)	
Median	1.78	2.07	4.36	3.43	
Min, Max	0.0, 7.1	0.0, 6.1	0.3, 9.1	0.0, 10.0	
C3D1 CFB					
n	22	35	45	82	
LS Mean (StdErr) [2]	-0.48 (0.325)	-0.67 (0.240)	-0.89 (0.280)	-1.15 (0.226)	
95% CI [2]	-1.13, 0.17	-1.15, -0.19	-1.44, -0.33	-1.60, -0.70	
Difference (95% CI) in CFB [2]		-0.19 (-0.89, 0.52)		-0.26 (-0.91, 0.39)	
p-value [3]		0.601		0.425	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	20	34	44	83	
Mean (StdDev)	2.39 (2.039)	2.20 (1.691)	4.19 (2.460)	3.63 (2.468)	
Median	2.30	1.96	4.18	3.33	
Min, Max	0.0, 6.8	0.0, 5.7	0.2, 8.4	0.0, 9.9	
C4D1 CFB					
n	20	34	44	83	
LS Mean (StdErr) [2]	0.08 (0.364)	-0.60 (0.263)	-1.19 (0.311)	-1.53 (0.247)	
95% CI [2]	-0.65, 0.81	-1.13, -0.07	-1.81, -0.57	-2.02, -1.04	
Difference (95% CI) in CFB [2]		-0.68 (-1.48, 0.12)		-0.34 (-1.05, 0.37)	
p-value [3]		0.093		0.345	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	36	44	83	
Mean (StdDev)	1.92 (1.629)	2.26 (1.675)	4.27 (2.454)	3.46 (2.505)	
Median	1.64	2.26	4.08	3.20	
Min, Max	0.0, 5.4	0.0, 5.6	0.0, 9.1	0.0, 10.0	
C5D1 CFB					
n	19	36	44	83	
LS Mean (StdErr) [2]	-0.55 (0.367)	-0.68 (0.253)	-1.11 (0.310)	-1.70 (0.247)	
95% CI [2]	-1.28, 0.19	-1.19, -0.17	-1.72, -0.49	-2.19, -1.21	
Difference (95% CI) in CFB [2]		-0.13 (-0.94, 0.67)		-0.60 (-1.30, 0.11)	
p-value [3]		0.744		0.098	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	20	37	42	81	
Mean (StdDev)	2.06 (1.691)	1.83 (1.584)	3.87 (2.589)	3.29 (2.608)	
Median	2.32	1.43	3.18	2.71	
Min, Max	0.0, 5.7	0.0, 6.0	0.0, 8.9	0.0, 10.0	
C6D1 CFB					
n	20	37	42	81	
LS Mean (StdErr) [2]	-0.41 (0.312)	-1.18 (0.218)	-1.40 (0.339)	-1.79 (0.267)	
95% CI [2]	-1.03, 0.22	-1.61, -0.74	-2.07, -0.73	-2.32, -1.26	
Difference (95% CI) in CFB [2]		-0.77 (-1.45, -0.09)		-0.40 (-1.17, 0.38)	
p-value [3]		0.027		0.314	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	19	36	43	79	
Mean (StdDev)	1.94 (1.766)	1.88 (1.521)	3.95 (2.704)	3.22 (2.593)	
Median	1.57	1.63	3.79	2.92	
Min, Max	0.0, 6.1	0.0, 4.9	0.0, 8.9	0.0, 10.0	
C7D1 CFB					
n	19	36	43	79	
LS Mean (StdErr) [2]	-0.48 (0.332)	-1.14 (0.229)	-1.33 (0.327)	-1.82 (0.264)	
95% CI [2]	-1.14, 0.19	-1.60, -0.68	-1.98, -0.68	-2.34, -1.29	
Difference (95% CI) in CFB [2]		-0.66 (-1.39, 0.07)		-0.49 (-1.24, 0.26)	
Hedges'G (95% CI) in CFB		-0.47 (-1.06, 0.09)		-0.21 (-0.59, 0.16)	
p-value [3]		0.074		0.202	
					0.744

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	22	37	45	86	
Mean (StdDev)	1.05 (1.014)	1.00 (0.716)	1.78 (1.645)	1.75 (1.948)	
Median	0.85	0.93	1.36	1.00	
Min, Max	0.0, 3.8	0.0, 2.6	0.0, 7.2	0.0, 12.2	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	22	35	45	84	
Mean (StdDev)	0.75 (0.813)	0.67 (0.644)	1.53 (1.406)	1.38 (1.662)	
Median	0.38	0.43	1.00	0.89	
Min, Max	0.0, 2.8	0.0, 2.3	0.0, 4.9	0.0, 10.7	
C2D1 CFB					
n	22	35	45	84	
LS Mean (StdErr) [2]	-0.31 (0.163)	-0.29 (0.120)	-0.37 (0.150)	-0.55 (0.121)	
95% CI [2]	-0.64, 0.02	-0.53, -0.05	-0.66, -0.07	-0.79, -0.31	
Difference (95% CI) in CFB [2]		0.02 (-0.33, 0.38)		-0.19 (-0.53, 0.16)	
p-value [3]		0.902		0.288	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	22	35	45	82	
Mean (StdDev)	0.79 (0.791)	0.75 (0.720)	1.37 (1.284)	1.16 (1.365)	
Median	0.43	0.50	0.92	0.79	
Min, Max	0.0, 2.3	0.0, 2.5	0.0, 4.4	0.0, 5.8	
C3D1 CFB					
n	22	35	45	82	
LS Mean (StdErr) [2]	-0.33 (0.170)	-0.24 (0.125)	-0.59 (0.204)	-0.85 (0.165)	
95% CI [2]	-0.67, 0.00	-0.49, 0.01	-0.99, -0.18	-1.17, -0.52	
Difference (95% CI) in CFB [2]		0.10 (-0.27, 0.47)		-0.26 (-0.73, 0.21)	
p-value [3]		0.608		0.277	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	20	34	44	83	
Mean (StdDev)	0.96 (1.004)	0.68 (0.699)	1.27 (1.201)	1.20 (1.611)	
Median	0.68	0.37	0.82	0.62	
Min, Max	0.0, 2.9	0.0, 2.3	0.0, 4.8	0.0, 9.0	
C4D1 CFB					
n	20	34	44	83	
LS Mean (StdErr) [2]	-0.15 (0.175)	-0.26 (0.126)	-0.69 (0.194)	-0.79 (0.154)	
95% CI [2]	-0.50, 0.20	-0.51, -0.00	-1.08, -0.31	-1.09, -0.48	
Difference (95% CI) in CFB [2]		-0.11 (-0.49, 0.28)		-0.10 (-0.54, 0.35)	
p-value [3]		0.573		0.670	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	36	44	83	
Mean (StdDev)	0.86 (0.948)	0.74 (0.831)	1.29 (1.278)	1.16 (1.697)	
Median	0.43	0.45	0.96	0.62	
Min, Max	0.0, 3.1	0.0, 3.1	0.0, 4.8	0.0, 9.6	
C5D1 CFB					
n	19	36	44	83	
LS Mean (StdErr) [2]	-0.23 (0.196)	-0.27 (0.135)	-0.74 (0.220)	-0.89 (0.174)	
95% CI [2]	-0.62, 0.16	-0.54, -0.00	-1.17, -0.30	-1.23, -0.54	
Difference (95% CI) in CFB [2]		-0.04 (-0.47, 0.39)		-0.15 (-0.65, 0.35)	
p-value [3]		0.840		0.548	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	20	37	42	81	
Mean (StdDev)	0.79 (1.005)	0.75 (0.814)	1.23 (1.400)	1.08 (1.487)	
Median	0.46	0.46	0.68	0.50	
Min, Max	0.0, 3.9	0.0, 3.3	0.0, 6.5	0.0, 9.0	
C6D1 CFB					
n	20	37	42	81	
LS Mean (StdErr) [2]	-0.34 (0.187)	-0.30 (0.131)	-0.66 (0.189)	-0.87 (0.149)	
95% CI [2]	-0.71, 0.04	-0.56, -0.03	-1.04, -0.29	-1.17, -0.58	
Difference (95% CI) in CFB [2]		0.04 (-0.37, 0.45)		-0.21 (-0.64, 0.22)	
p-value [3]		0.845		0.336	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	19	36	43	79	
Mean (StdDev)	0.65 (0.676)	0.66 (0.767)	1.27 (1.413)	0.97 (1.227)	
Median	0.50	0.35	0.79	0.29	
Min, Max	0.0, 2.3	0.0, 2.8	0.0, 5.9	0.0, 4.8	
C7D1 CFB					
n	19	36	43	79	
LS Mean (StdErr) [2]	-0.38 (0.169)	-0.35 (0.116)	-0.61 (0.209)	-0.86 (0.169)	
95% CI [2]	-0.72, -0.04	-0.58, -0.11	-1.02, -0.19	-1.20, -0.53	
Difference (95% CI) in CFB [2]		0.03 (-0.34, 0.40)		-0.25 (-0.73, 0.23)	
Hedges'G (95% CI) in CFB		0.04 (-0.52, 0.61)		-0.17 (-0.55, 0.20)	
p-value [3]		0.866		0.296	
					0.401

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	22	37	45	86	
Mean (StdDev)	1.65 (1.591)	2.28 (1.593)	3.94 (2.721)	3.39 (2.641)	
Median	1.29	2.21	4.00	2.89	
Min, Max	0.0, 5.3	0.0, 7.0	0.0, 9.5	0.0, 9.5	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	22	35	45	84	
Mean (StdDev)	1.17 (1.083)	1.57 (1.692)	3.11 (2.628)	2.72 (2.524)	
Median	0.74	1.00	2.64	2.00	
Min, Max	0.0, 3.4	0.0, 6.6	0.0, 9.1	0.0, 8.9	
C2D1 CFB					
n	22	35	45	84	
LS Mean (StdErr) [2]	-0.43 (0.288)	-0.63 (0.213)	-0.76 (0.245)	-0.63 (0.197)	
95% CI [2]	-1.00, 0.15	-1.05, -0.20	-1.25, -0.28	-1.02, -0.24	
Difference (95% CI) in CFB [2]		-0.20 (-0.83, 0.43)		0.13 (-0.43, 0.69)	
p-value [3]		0.527		0.647	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	22	35	45	82	
Mean (StdDev)	1.17 (1.099)	1.81 (1.921)	2.91 (2.513)	2.33 (2.349)	
Median	0.89	0.93	2.00	1.67	
Min, Max	0.0, 3.1	0.0, 6.9	0.0, 8.7	0.0, 9.5	
C3D1 CFB					
n	22	35	45	82	
LS Mean (StdErr) [2]	-0.53 (0.313)	-0.46 (0.231)	-1.02 (0.308)	-1.09 (0.250)	
95% CI [2]	-1.16, 0.10	-0.92, 0.01	-1.63, -0.41	-1.59, -0.60	
Difference (95% CI) in CFB [2]		0.08 (-0.61, 0.76)		-0.08 (-0.79, 0.63)	
p-value [3]		0.822		0.828	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	20	34	44	83	
Mean (StdDev)	1.47 (1.478)	1.50 (1.589)	3.02 (2.535)	2.34 (2.521)	
Median	1.15	0.86	2.46	1.36	
Min, Max	0.0, 4.6	0.0, 6.6	0.0, 8.3	0.0, 8.9	
C4D1 CFB					
n	20	34	44	83	
LS Mean (StdErr) [2]	-0.14 (0.310)	-0.64 (0.224)	-0.97 (0.304)	-1.11 (0.241)	
95% CI [2]	-0.76, 0.49	-1.09, -0.19	-1.57, -0.37	-1.59, -0.63	
Difference (95% CI) in CFB [2]		-0.51 (-1.19, 0.18)		-0.14 (-0.83, 0.55)	
p-value [3]		0.143		0.688	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	36	44	83	
Mean (StdDev)	1.33 (1.284)	1.61 (1.774)	2.95 (2.584)	2.18 (2.418)	
Median	1.00	0.78	2.19	1.31	
Min, Max	0.0, 4.3	0.0, 6.9	0.0, 8.5	0.0, 9.0	
C5D1 CFB					
n	19	36	44	83	
LS Mean (StdErr) [2]	-0.34 (0.341)	-0.65 (0.235)	-1.11 (0.342)	-1.36 (0.272)	
95% CI [2]	-1.02, 0.35	-1.12, -0.17	-1.79, -0.44	-1.90, -0.82	
Difference (95% CI) in CFB [2]		-0.31 (-1.06, 0.44)		-0.24 (-1.02, 0.53)	
p-value [3]		0.411		0.536	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	20	37	42	81	
Mean (StdDev)	1.32 (1.379)	1.62 (1.798)	2.75 (2.607)	2.07 (2.400)	
Median	0.93	1.08	2.11	1.21	
Min, Max	0.0, 4.4	0.0, 7.5	0.0, 8.6	0.0, 8.9	
C6D1 CFB					
n	20	37	42	81	
LS Mean (StdErr) [2]	-0.20 (0.336)	-0.66 (0.234)	-1.15 (0.327)	-1.36 (0.257)	
95% CI [2]	-0.87, 0.48	-1.13, -0.19	-1.80, -0.50	-1.87, -0.85	
Difference (95% CI) in CFB [2]		-0.46 (-1.19, 0.27)		-0.21 (-0.96, 0.54)	
p-value [3]		0.214		0.575	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.5a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	19	36	43	79	
Mean (StdDev)	1.10 (1.189)	1.52 (1.623)	2.78 (2.723)	2.02 (2.490)	
Median	0.50	0.75	1.85	0.77	
Min, Max	0.0, 3.4	0.0, 6.6	0.0, 8.6	0.0, 8.7	
C7D1 CFB					
n	19	36	43	79	
LS Mean (StdErr) [2]	-0.34 (0.320)	-0.71 (0.221)	-1.15 (0.358)	-1.40 (0.289)	
95% CI [2]	-0.98, 0.31	-1.15, -0.27	-1.86, -0.44	-1.97, -0.82	
Difference (95% CI) in CFB [2]		-0.38 (-1.08, 0.33)		-0.25 (-1.07, 0.58)	
Hedges'G (95% CI) in CFB		-0.28 (-0.86, 0.28)		-0.10 (-0.47, 0.28)	
p-value [3]		0.287		0.555	
					0.838

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	13	26	54	97	
Mean (StdDev)	5.71 (2.590)	5.23 (2.972)	5.50 (2.399)	5.71 (2.232)	
Median	5.50	5.46	5.79	6.08	
Min, Max	0.7, 9.4	0.0, 9.9	0.0, 10.0	0.0, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	54	94	
Mean (StdDev)	4.46 (2.351)	4.93 (2.912)	5.05 (2.639)	4.84 (2.490)	
Median	4.67	5.07	5.37	4.77	
Min, Max	0.6, 7.8	0.0, 9.7	0.0, 10.0	0.0, 10.0	
C2D1 CFB					
n	13	25	54	94	
LS Mean (StdErr) [2]	-1.36 (0.348)	-0.50 (0.236)	-0.40 (0.174)	-0.78 (0.139)	
95% CI [2]	-2.06, -0.65	-0.97, -0.02	-0.75, -0.06	-1.05, -0.50	
Difference (95% CI) in CFB [2]		0.86 (0.05, 1.67)		-0.38 (-0.80, 0.05)	
p-value [3]		0.038		0.083	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	25	54	92	
Mean (StdDev)	4.47 (2.473)	4.44 (2.964)	4.93 (2.705)	4.56 (2.613)	
Median	4.43	4.29	5.44	4.29	
Min, Max	0.0, 8.1	0.0, 9.0	0.0, 10.0	0.0, 10.0	
C3D1 CFB					
n	13	25	54	92	
LS Mean (StdErr) [2]	-1.27 (0.436)	-0.95 (0.295)	-0.53 (0.206)	-1.04 (0.166)	
95% CI [2]	-2.16, -0.39	-1.55, -0.35	-0.94, -0.12	-1.37, -0.71	
Difference (95% CI) in CFB [2]		0.32 (-0.69, 1.34)		-0.51 (-1.02, -0.00)	
p-value [3]		0.521		0.048	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	12	25	52	92	
Mean (StdDev)	4.88 (2.643)	4.62 (2.872)	4.85 (2.785)	4.49 (2.785)	
Median	5.39	4.21	4.63	4.18	
Min, Max	0.1, 7.7	0.0, 9.0	0.0, 9.8	0.0, 10.0	
C4D1 CFB					
n	12	25	52	92	
LS Mean (StdErr) [2]	-0.65 (0.559)	-0.68 (0.368)	-0.73 (0.249)	-1.17 (0.198)	
95% CI [2]	-1.79, 0.49	-1.42, 0.07	-1.22, -0.23	-1.56, -0.78	
Difference (95% CI) in CFB [2]		-0.03 (-1.32, 1.27)		-0.44 (-1.05, 0.16)	
p-value [3]		0.968		0.152	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	26	51	93	
Mean (StdDev)	4.78 (2.406)	4.46 (2.875)	4.87 (2.823)	4.19 (2.802)	
Median	5.11	4.53	4.86	4.14	
Min, Max	0.3, 8.1	0.0, 9.8	0.0, 9.8	0.0, 10.0	
C5D1 CFB					
n	12	26	51	93	
LS Mean (StdErr) [2]	-0.73 (0.505)	-0.69 (0.324)	-0.70 (0.276)	-1.44 (0.214)	
95% CI [2]	-1.76, 0.29	-1.35, -0.04	-1.24, -0.15	-1.86, -1.02	
Difference (95% CI) in CFB [2]		0.04 (-1.13, 1.21)		-0.75 (-1.41, -0.08)	
p-value [3]		0.945		0.028	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	26	50	92	
Mean (StdDev)	4.72 (2.569)	4.37 (2.818)	4.83 (2.767)	4.02 (2.731)	
Median	5.23	4.26	5.04	3.75	
Min, Max	0.3, 8.4	0.0, 9.5	0.0, 9.6	0.0, 10.0	
C6D1 CFB					
n	12	26	50	92	
LS Mean (StdErr) [2]	-0.71 (0.561)	-0.76 (0.360)	-0.58 (0.275)	-1.56 (0.212)	
95% CI [2]	-1.85, 0.43	-1.49, -0.03	-1.12, -0.03	-1.98, -1.14	
Difference (95% CI) in CFB [2]		-0.05 (-1.35, 1.26)		-0.98 (-1.65, -0.32)	
p-value [3]		0.942		0.004	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	12	25	50	90	
Mean (StdDev)	4.55 (2.734)	4.19 (2.969)	4.80 (2.736)	3.97 (2.779)	
Median	5.05	3.64	5.35	3.63	
Min, Max	0.3, 8.8	0.0, 9.7	0.0, 9.4	0.0, 10.0	
C7D1 CFB					
n	12	25	50	90	
LS Mean (StdErr) [2]	-0.88 (0.654)	-0.84 (0.425)	-0.67 (0.278)	-1.57 (0.216)	
95% CI [2]	-2.21, 0.45	-1.70, 0.03	-1.21, -0.12	-1.99, -1.14	
Difference (95% CI) in CFB [2]		0.04 (-1.50, 1.58)		-0.90 (-1.57, -0.23)	
Hedges'G (95% CI) in CFB		0.02 (-0.69, 0.73)		-0.44 (-0.80, -0.10)	
p-value [3]		0.958		0.009	
					0.197

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	13	26	54	97	
Mean (StdDev)	5.21 (2.150)	3.98 (2.436)	3.93 (2.426)	4.21 (2.126)	
Median	4.55	3.69	4.11	4.08	
Min, Max	1.7, 8.2	0.5, 8.8	0.0, 9.6	0.0, 9.8	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	54	94	
Mean (StdDev)	3.78 (2.228)	3.56 (2.630)	3.28 (2.186)	3.32 (2.028)	
Median	3.57	2.71	3.18	3.16	
Min, Max	0.2, 7.6	0.1, 9.4	0.0, 8.9	0.0, 8.0	
C2D1 CFB					
n	13	25	54	94	
LS Mean (StdErr) [2]	-1.36 (0.394)	-0.44 (0.267)	-0.60 (0.151)	-0.82 (0.121)	
95% CI [2]	-2.16, -0.57	-0.98, 0.10	-0.90, -0.30	-1.06, -0.58	
Difference (95% CI) in CFB [2]		0.93 (0.01, 1.84)		-0.22 (-0.60, 0.15)	
p-value [3]		0.048		0.238	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	25	54	92	
Mean (StdDev)	3.24 (2.096)	3.23 (2.407)	3.16 (2.277)	2.86 (2.121)	
Median	2.82	3.00	3.14	2.66	
Min, Max	0.5, 7.2	0.0, 8.3	0.0, 8.4	0.0, 8.3	
C3D1 CFB					
n	13	25	54	92	
LS Mean (StdErr) [2]	-1.87 (0.367)	-0.76 (0.249)	-0.67 (0.205)	-1.16 (0.165)	
95% CI [2]	-2.62, -1.13	-1.27, -0.26	-1.07, -0.26	-1.49, -0.83	
Difference (95% CI) in CFB [2]		1.11 (0.25, 1.96)		-0.49 (-1.00, 0.01)	
p-value [3]		0.013		0.055	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	12	25	52	92	
Mean (StdDev)	3.32 (2.009)	3.01 (2.298)	3.12 (2.232)	2.58 (2.175)	
Median	3.32	2.45	3.15	2.07	
Min, Max	0.6, 6.6	0.0, 9.1	0.0, 7.9	0.0, 8.4	
C4D1 CFB					
n	12	25	52	92	
LS Mean (StdErr) [2]	-1.77 (0.476)	-0.89 (0.314)	-0.81 (0.244)	-1.53 (0.194)	
95% CI [2]	-2.74, -0.80	-1.53, -0.26	-1.30, -0.33	-1.91, -1.14	
Difference (95% CI) in CFB [2]		0.88 (-0.23, 1.98)		-0.72 (-1.31, -0.12)	
p-value [3]		0.117		0.019	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	26	51	93	
Mean (StdDev)	3.20 (1.770)	2.95 (2.275)	3.25 (2.300)	2.47 (2.292)	
Median	2.93	2.35	3.00	1.85	
Min, Max	0.7, 5.9	0.0, 7.6	0.0, 8.1	0.0, 9.4	
C5D1 CFB					
n	12	26	51	93	
LS Mean (StdErr) [2]	-1.79 (0.546)	-0.90 (0.351)	-0.68 (0.270)	-1.61 (0.210)	
95% CI [2]	-2.90, -0.68	-1.61, -0.18	-1.22, -0.15	-2.03, -1.20	
Difference (95% CI) in CFB [2]		0.90 (-0.37, 2.17)		-0.93 (-1.58, -0.28)	
p-value [3]		0.161		0.005	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	26	50	92	
Mean (StdDev)	2.94 (2.045)	2.73 (2.488)	2.65 (2.122)	2.34 (2.212)	
Median	2.84	2.30	2.35	1.82	
Min, Max	0.0, 5.8	0.0, 9.6	0.0, 7.1	0.0, 8.9	
C6D1 CFB					
n	12	26	50	92	
LS Mean (StdErr) [2]	-2.08 (0.641)	-1.12 (0.411)	-1.05 (0.267)	-1.65 (0.206)	
95% CI [2]	-3.38, -0.78	-1.96, -0.29	-1.58, -0.52	-2.06, -1.25	
Difference (95% CI) in CFB [2]		0.96 (-0.53, 2.45)		-0.60 (-1.25, 0.04)	
p-value [3]		0.201		0.067	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	12	25	50	90	
Mean (StdDev)	3.05 (1.802)	2.69 (2.383)	2.85 (2.430)	2.39 (2.190)	
Median	2.95	2.00	2.45	2.00	
Min, Max	0.2, 5.8	0.0, 9.4	0.0, 8.3	0.0, 8.6	
C7D1 CFB					
n	12	25	50	90	
LS Mean (StdErr) [2]	-1.96 (0.596)	-1.09 (0.387)	-0.92 (0.266)	-1.63 (0.207)	
95% CI [2]	-3.17, -0.75	-1.87, -0.30	-1.45, -0.40	-2.04, -1.22	
Difference (95% CI) in CFB [2]		0.87 (-0.53, 2.27)		-0.71 (-1.35, -0.06)	
Hedges'G (95% CI) in CFB		0.43 (-0.26, 1.18)		-0.36 (-0.72, -0.02)	
p-value [3]		0.215		0.031	
					0.026

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	13	26	54	97	
Mean (StdDev)	4.53 (2.474)	3.39 (2.915)	3.30 (2.428)	3.16 (2.419)	
Median	5.08	2.74	2.89	2.83	
Min, Max	1.0, 8.6	0.0, 8.9	0.0, 8.9	0.0, 9.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	54	94	
Mean (StdDev)	3.10 (2.227)	3.45 (2.690)	2.97 (2.410)	2.54 (2.239)	
Median	2.25	2.64	2.77	2.27	
Min, Max	0.5, 7.4	0.0, 8.8	0.0, 8.3	0.0, 8.2	
C2D1 CFB					
n	13	25	54	94	
LS Mean (StdErr) [2]	-1.23 (0.336)	0.05 (0.227)	-0.29 (0.171)	-0.53 (0.137)	
95% CI [2]	-1.91, -0.55	-0.41, 0.51	-0.63, 0.05	-0.80, -0.26	
Difference (95% CI) in CFB [2]		1.28 (0.49, 2.06)		-0.24 (-0.66, 0.18)	
p-value [3]		0.002		0.254	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	25	54	92	
Mean (StdDev)	2.32 (2.187)	3.07 (2.527)	2.73 (2.343)	2.25 (2.194)	
Median	1.54	2.62	2.43	1.78	
Min, Max	0.0, 7.0	0.0, 8.9	0.0, 7.7	0.0, 7.9	
C3D1 CFB					
n	13	25	54	92	
LS Mean (StdErr) [2]	-1.85 (0.385)	-0.27 (0.261)	-0.50 (0.207)	-0.75 (0.167)	
95% CI [2]	-2.64, -1.07	-0.80, 0.26	-0.90, -0.09	-1.08, -0.42	
Difference (95% CI) in CFB [2]		1.58 (0.69, 2.48)		-0.26 (-0.77, 0.25)	
p-value [3]		0.001		0.323	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	12	25	52	92	
Mean (StdDev)	2.28 (2.037)	2.73 (2.480)	2.84 (2.277)	1.99 (2.168)	
Median	1.75	2.14	2.64	1.30	
Min, Max	0.0, 6.6	0.0, 9.2	0.0, 7.4	0.0, 8.4	
C4D1 CFB					
n	12	25	52	92	
LS Mean (StdErr) [2]	-2.00 (0.419)	-0.58 (0.276)	-0.47 (0.242)	-1.03 (0.192)	
95% CI [2]	-2.85, -1.14	-1.14, -0.02	-0.94, 0.01	-1.41, -0.65	
Difference (95% CI) in CFB [2]		1.42 (0.44, 2.39)		-0.57 (-1.15, 0.02)	
p-value [3]		0.006		0.059	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	26	51	93	
Mean (StdDev)	2.23 (1.992)	2.67 (2.382)	2.93 (2.256)	1.97 (2.200)	
Median	1.93	2.12	2.85	1.29	
Min, Max	0.1, 6.1	0.0, 8.4	0.0, 8.5	0.0, 8.9	
C5D1 CFB					
n	12	26	51	93	
LS Mean (StdErr) [2]	-1.90 (0.549)	-0.53 (0.352)	-0.41 (0.256)	-1.04 (0.199)	
95% CI [2]	-3.01, -0.78	-1.24, 0.19	-0.92, 0.10	-1.43, -0.65	
Difference (95% CI) in CFB [2]		1.37 (0.10, 2.65)		-0.63 (-1.25, -0.01)	
p-value [3]		0.036		0.046	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	26	50	92	
Mean (StdDev)	1.95 (2.053)	2.30 (2.507)	2.58 (2.121)	1.79 (2.084)	
Median	1.11	1.64	2.43	1.36	
Min, Max	0.1, 6.4	0.0, 9.9	0.0, 7.9	0.0, 8.9	
C6D1 CFB					
n	12	26	50	92	
LS Mean (StdErr) [2]	-2.24 (0.557)	-0.92 (0.357)	-0.65 (0.257)	-1.14 (0.198)	
95% CI [2]	-3.37, -1.11	-1.65, -0.20	-1.16, -0.15	-1.54, -0.75	
Difference (95% CI) in CFB [2]		1.32 (0.03, 2.61)		-0.49 (-1.11, 0.13)	
p-value [3]		0.046		0.123	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	12	25	50	90	
Mean (StdDev)	2.27 (1.942)	2.25 (2.356)	2.63 (2.352)	1.86 (2.138)	
Median	1.57	1.82	2.52	1.23	
Min, Max	0.1, 5.9	0.0, 9.5	0.0, 7.7	0.0, 8.3	
C7D1 CFB					
n	12	25	50	90	
LS Mean (StdErr) [2]	-1.81 (0.624)	-0.84 (0.405)	-0.63 (0.278)	-1.10 (0.216)	
95% CI [2]	-3.08, -0.54	-1.66, -0.01	-1.18, -0.08	-1.53, -0.67	
Difference (95% CI) in CFB [2]		0.97 (-0.49, 2.44)		-0.47 (-1.14, 0.20)	
Hedges'G (95% CI) in CFB		0.46 (-0.23, 1.21)		-0.23 (-0.59, 0.11)	
p-value [3]		0.185		0.168	
					0.038

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	13	26	54	97	
Mean (StdDev)	5.83 (2.361)	5.17 (3.305)	6.09 (3.172)	5.65 (2.944)	
Median	7.00	5.46	6.60	6.07	
Min, Max	0.0, 8.5	0.0, 10.0	0.0, 10.0	0.0, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	54	94	
Mean (StdDev)	5.04 (2.166)	4.44 (2.881)	5.77 (3.002)	4.70 (2.739)	
Median	5.71	4.67	6.04	4.79	
Min, Max	0.0, 6.9	0.0, 10.0	0.0, 10.0	0.0, 9.9	
C2D1 CFB					
n	13	25	54	94	
LS Mean (StdErr) [2]	-0.70 (0.414)	-0.73 (0.281)	-0.27 (0.165)	-0.88 (0.132)	
95% CI [2]	-1.54, 0.14	-1.30, -0.16	-0.59, 0.06	-1.14, -0.62	
Difference (95% CI) in CFB [2]		-0.03 (-0.99, 0.94)		-0.62 (-1.02, -0.21)	
p-value [3]		0.954		0.003	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	25	54	92	
Mean (StdDev)	4.82 (2.286)	4.28 (2.759)	5.76 (3.035)	4.20 (2.576)	
Median	5.18	4.46	5.76	3.93	
Min, Max	0.0, 8.7	0.0, 8.9	0.0, 10.0	0.0, 9.8	
C3D1 CFB					
n	13	25	54	92	
LS Mean (StdErr) [2]	-0.89 (0.419)	-0.88 (0.284)	-0.23 (0.213)	-1.35 (0.172)	
95% CI [2]	-1.74, -0.04	-1.46, -0.31	-0.65, 0.19	-1.69, -1.01	
Difference (95% CI) in CFB [2]		0.01 (-0.97, 0.99)		-1.12 (-1.65, -0.60)	
p-value [3]		0.986		<0.0001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	12	25	52	92	
Mean (StdDev)	4.98 (2.340)	4.42 (2.682)	5.62 (3.051)	3.87 (2.576)	
Median	5.32	4.92	5.75	3.55	
Min, Max	0.0, 8.9	0.0, 8.9	0.0, 10.0	0.0, 9.4	
C4D1 CFB					
n	12	25	52	92	
LS Mean (StdErr) [2]	-0.70 (0.440)	-0.72 (0.290)	-0.32 (0.226)	-1.68 (0.180)	
95% CI [2]	-1.59, 0.20	-1.31, -0.13	-0.77, 0.13	-2.04, -1.33	
Difference (95% CI) in CFB [2]		-0.03 (-1.05, 0.99)		-1.36 (-1.91, -0.81)	
p-value [3]		0.957		<0.0001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	26	51	93	
Mean (StdDev)	4.56 (2.267)	4.03 (2.773)	5.60 (3.030)	3.68 (2.522)	
Median	4.61	4.42	5.21	3.07	
Min, Max	0.0, 9.0	0.1, 9.9	0.0, 10.0	0.0, 9.3	
C5D1 CFB					
n	12	26	51	93	
LS Mean (StdErr) [2]	-1.17 (0.464)	-1.09 (0.298)	-0.29 (0.248)	-1.79 (0.193)	
95% CI [2]	-2.11, -0.23	-1.70, -0.49	-0.78, 0.21	-2.17, -1.41	
Difference (95% CI) in CFB [2]		0.08 (-1.00, 1.15)		-1.50 (-2.10, -0.90)	
p-value [3]		0.887		<0.0001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	26	50	92	
Mean (StdDev)	4.50 (2.045)	4.33 (2.854)	5.71 (3.060)	3.39 (2.472)	
Median	4.71	4.80	5.35	3.07	
Min, Max	0.0, 8.8	0.0, 10.0	0.0, 10.0	0.0, 10.0	
C6D1 CFB					
n	12	26	50	92	
LS Mean (StdErr) [2]	-1.41 (0.624)	-0.86 (0.400)	-0.22 (0.275)	-2.06 (0.212)	
95% CI [2]	-2.68, -0.14	-1.67, -0.05	-0.76, 0.33	-2.48, -1.64	
Difference (95% CI) in CFB [2]		0.55 (-0.90, 2.00)		-1.84 (-2.51, -1.18)	
p-value [3]		0.447		<0.0001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	12	25	50	90	
Mean (StdDev)	4.35 (2.216)	4.26 (2.986)	5.79 (2.932)	3.37 (2.552)	
Median	4.11	4.83	5.41	3.04	
Min, Max	0.0, 9.4	0.0, 10.0	0.0, 10.0	0.0, 10.0	
C7D1 CFB					
n	12	25	50	90	
LS Mean (StdErr) [2]	-1.53 (0.669)	-1.01 (0.435)	-0.27 (0.282)	-2.08 (0.219)	
95% CI [2]	-2.89, -0.17	-1.89, -0.12	-0.82, 0.29	-2.51, -1.64	
Difference (95% CI) in CFB [2]		0.52 (-1.05, 2.09)		-1.81 (-2.49, -1.13)	
Hedges'G (95% CI) in CFB		0.23 (-0.47, 0.96)		-0.88 (-1.26, -0.53)	
p-value [3]		0.503		<0.0001	
					0.008

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	13	26	54	97	
Mean (StdDev)	5.77 (1.843)	5.85 (2.332)	6.02 (2.813)	5.35 (2.764)	
Median	6.36	5.56	6.46	5.86	
Min, Max	2.5, 7.9	1.9, 10.0	0.0, 10.0	0.0, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	54	94	
Mean (StdDev)	4.56 (2.127)	4.60 (2.455)	5.46 (2.856)	4.30 (2.354)	
Median	4.43	4.83	5.89	4.26	
Min, Max	1.3, 7.5	0.0, 9.6	0.0, 10.0	0.0, 9.9	
C2D1 CFB					
n	13	25	54	94	
LS Mean (StdErr) [2]	-1.28 (0.521)	-1.31 (0.352)	-0.51 (0.214)	-0.98 (0.172)	
95% CI [2]	-2.34, -0.22	-2.02, -0.59	-0.93, -0.08	-1.32, -0.64	
Difference (95% CI) in CFB [2]		-0.03 (-1.24, 1.19)		-0.47 (-1.00, 0.05)	
p-value [3]		0.965		0.079	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	25	54	92	
Mean (StdDev)	4.34 (2.026)	4.18 (2.497)	5.16 (2.877)	3.54 (2.421)	
Median	4.77	4.43	5.11	3.26	
Min, Max	1.1, 7.0	0.0, 9.7	0.0, 10.0	0.0, 9.1	
C3D1 CFB					
n	13	25	54	92	
LS Mean (StdErr) [2]	-1.40 (0.572)	-1.69 (0.387)	-0.73 (0.269)	-1.62 (0.217)	
95% CI [2]	-2.56, -0.24	-2.47, -0.90	-1.27, -0.20	-2.05, -1.19	
Difference (95% CI) in CFB [2]		-0.29 (-1.62, 1.05)		-0.88 (-1.55, -0.22)	
p-value [3]		0.665		0.009	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	12	25	52	92	
Mean (StdDev)	4.18 (2.130)	4.09 (2.540)	5.08 (2.926)	3.26 (2.529)	
Median	4.32	4.29	5.22	3.04	
Min, Max	0.0, 6.8	0.0, 9.3	0.0, 10.0	0.0, 10.0	
C4D1 CFB					
n	12	25	52	92	
LS Mean (StdErr) [2]	-1.62 (0.682)	-1.77 (0.449)	-0.92 (0.322)	-2.00 (0.255)	
95% CI [2]	-3.00, -0.23	-2.68, -0.86	-1.56, -0.28	-2.51, -1.50	
Difference (95% CI) in CFB [2]		-0.15 (-1.74, 1.43)		-1.08 (-1.87, -0.30)	
p-value [3]		0.846		0.007	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	26	51	93	
Mean (StdDev)	4.00 (1.836)	3.90 (2.537)	5.26 (2.772)	2.98 (2.487)	
Median	4.32	3.82	5.36	2.86	
Min, Max	0.1, 6.2	0.0, 9.2	0.0, 10.0	0.0, 10.0	
C5D1 CFB					
n	12	26	51	93	
LS Mean (StdErr) [2]	-1.73 (0.728)	-1.90 (0.467)	-0.68 (0.333)	-2.12 (0.258)	
95% CI [2]	-3.21, -0.25	-2.85, -0.95	-1.34, -0.03	-2.63, -1.61	
Difference (95% CI) in CFB [2]		-0.17 (-1.86, 1.52)		-1.43 (-2.24, -0.63)	
p-value [3]		0.839		<0.001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	26	50	92	
Mean (StdDev)	3.93 (1.967)	3.63 (2.637)	5.18 (2.776)	2.96 (2.511)	
Median	4.18	3.11	5.04	2.54	
Min, Max	0.0, 6.0	0.0, 9.9	0.0, 10.0	0.0, 10.0	
C6D1 CFB					
n	12	26	50	92	
LS Mean (StdErr) [2]	-1.73 (0.760)	-2.15 (0.488)	-0.78 (0.339)	-2.21 (0.261)	
95% CI [2]	-3.27, -0.19	-3.14, -1.16	-1.45, -0.11	-2.72, -1.69	
Difference (95% CI) in CFB [2]		-0.42 (-2.19, 1.34)		-1.43 (-2.25, -0.61)	
p-value [3]		0.630		<0.001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	12	25	50	90	
Mean (StdDev)	4.04 (1.976)	3.52 (2.626)	5.29 (2.632)	2.91 (2.470)	
Median	4.21	3.00	5.22	2.70	
Min, Max	0.0, 6.6	0.0, 9.6	0.2, 10.0	0.0, 10.0	
C7D1 CFB					
n	12	25	50	90	
LS Mean (StdErr) [2]	-1.59 (0.742)	-2.23 (0.482)	-0.78 (0.362)	-2.25 (0.282)	
95% CI [2]	-3.10, -0.09	-3.21, -1.25	-1.50, -0.06	-2.80, -1.69	
Difference (95% CI) in CFB [2]		-0.64 (-2.38, 1.10)		-1.46 (-2.34, -0.59)	
Hedges'G (95% CI) in CFB		-0.25 (-0.99, 0.45)		-0.55 (-0.92, -0.21)	
p-value [3]		0.461		0.001	
					0.460

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	13	26	54	97	
Mean (StdDev)	6.13 (2.074)	5.66 (2.553)	5.89 (2.669)	5.32 (2.377)	
Median	6.64	5.69	5.67	5.43	
Min, Max	2.3, 9.2	0.0, 9.8	0.0, 10.0	0.0, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	54	94	
Mean (StdDev)	5.35 (2.332)	4.86 (2.559)	5.40 (2.720)	4.64 (2.446)	
Median	4.64	4.83	5.11	4.78	
Min, Max	1.5, 9.0	0.0, 10.0	0.0, 10.0	0.0, 9.9	
C2D1 CFB					
n	13	25	54	94	
LS Mean (StdErr) [2]	-0.80 (0.496)	-0.85 (0.336)	-0.45 (0.196)	-0.62 (0.157)	
95% CI [2]	-1.80, 0.21	-1.53, -0.17	-0.83, -0.06	-0.93, -0.31	
Difference (95% CI) in CFB [2]		-0.05 (-1.20, 1.11)		-0.17 (-0.66, 0.31)	
p-value [3]		0.931		0.477	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	25	54	92	
Mean (StdDev)	5.21 (2.578)	4.46 (2.673)	5.19 (2.868)	4.06 (2.467)	
Median	4.92	4.38	5.35	3.95	
Min, Max	0.9, 9.4	0.2, 10.0	0.0, 10.0	0.0, 10.0	
C3D1 CFB					
n	13	25	54	92	
LS Mean (StdErr) [2]	-0.99 (0.607)	-1.26 (0.411)	-0.61 (0.235)	-1.16 (0.190)	
95% CI [2]	-2.23, 0.24	-2.10, -0.43	-1.07, -0.14	-1.53, -0.78	
Difference (95% CI) in CFB [2]		-0.27 (-1.68, 1.15)		-0.55 (-1.13, 0.03)	
p-value [3]		0.701		0.062	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	12	25	52	92	
Mean (StdDev)	5.04 (2.758)	4.14 (2.654)	5.19 (2.896)	3.86 (2.501)	
Median	4.14	3.54	5.36	3.78	
Min, Max	1.6, 9.4	0.0, 10.0	0.0, 10.0	0.0, 9.9	
C4D1 CFB					
n	12	25	52	92	
LS Mean (StdErr) [2]	-1.05 (0.694)	-1.53 (0.457)	-0.67 (0.274)	-1.42 (0.218)	
95% CI [2]	-2.46, 0.36	-2.46, -0.60	-1.22, -0.13	-1.85, -0.99	
Difference (95% CI) in CFB [2]		-0.48 (-2.09, 1.13)		-0.75 (-1.42, -0.08)	
p-value [3]		0.548		0.028	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	26	51	93	
Mean (StdDev)	4.81 (2.802)	3.87 (2.628)	5.29 (2.873)	3.69 (2.530)	
Median	4.75	4.00	5.43	3.71	
Min, Max	0.3, 9.4	0.0, 9.7	0.0, 10.0	0.0, 9.8	
C5D1 CFB					
n	12	26	51	93	
LS Mean (StdErr) [2]	-1.22 (0.785)	-1.75 (0.504)	-0.56 (0.303)	-1.55 (0.235)	
95% CI [2]	-2.81, 0.38	-2.78, -0.73	-1.16, 0.04	-2.02, -1.08	
Difference (95% CI) in CFB [2]		-0.53 (-2.36, 1.29)		-0.99 (-1.72, -0.26)	
p-value [3]		0.556		0.008	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	26	50	92	
Mean (StdDev)	4.79 (2.583)	3.63 (2.709)	5.11 (2.971)	3.59 (2.558)	
Median	4.46	3.54	5.14	3.39	
Min, Max	0.6, 8.8	0.0, 9.8	0.0, 10.0	0.0, 10.0	
C6D1 CFB					
n	12	26	50	92	
LS Mean (StdErr) [2]	-1.16 (0.798)	-1.97 (0.512)	-0.78 (0.318)	-1.68 (0.245)	
95% CI [2]	-2.78, 0.46	-3.01, -0.93	-1.41, -0.15	-2.16, -1.19	
Difference (95% CI) in CFB [2]		-0.81 (-2.67, 1.04)		-0.90 (-1.67, -0.13)	
p-value [3]		0.381		0.023	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	12	25	50	90	
Mean (StdDev)	5.01 (2.613)	3.59 (2.613)	5.15 (2.902)	3.29 (2.541)	
Median	5.27	3.67	5.25	2.89	
Min, Max	0.9, 9.4	0.0, 9.6	0.0, 10.0	0.0, 10.0	
C7D1 CFB					
n	12	25	50	90	
LS Mean (StdErr) [2]	-0.84 (0.836)	-1.94 (0.543)	-0.88 (0.329)	-1.93 (0.256)	
95% CI [2]	-2.54, 0.86	-3.05, -0.84	-1.53, -0.23	-2.44, -1.42	
Difference (95% CI) in CFB [2]		-1.10 (-3.07, 0.86)		-1.05 (-1.84, -0.25)	
Hedges'G (95% CI) in CFB		-0.39 (-1.13, 0.30)		-0.43 (-0.79, -0.09)	
p-value [3]		0.261		0.010	
					0.995

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	13	26	54	97	
Mean (StdDev)	7.27 (1.878)	7.15 (1.965)	6.67 (2.030)	6.89 (1.999)	
Median	6.86	7.30	6.68	7.07	
Min, Max	4.8, 10.0	1.5, 10.0	0.0, 10.0	0.1, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	54	94	
Mean (StdDev)	6.56 (1.955)	6.45 (2.194)	6.33 (1.942)	6.22 (2.213)	
Median	6.29	6.58	6.30	6.25	
Min, Max	3.5, 9.8	0.7, 10.0	2.3, 10.0	0.1, 10.0	
C2D1 CFB					
n	13	25	54	94	
LS Mean (StdErr) [2]	-0.70 (0.450)	-0.75 (0.305)	-0.32 (0.159)	-0.65 (0.128)	
95% CI [2]	-1.62, 0.21	-1.37, -0.13	-0.64, -0.01	-0.90, -0.39	
Difference (95% CI) in CFB [2]		-0.05 (-1.10, 1.00)		-0.33 (-0.72, 0.07)	
p-value [3]		0.926		0.102	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	25	54	92	
Mean (StdDev)	6.23 (2.407)	6.05 (2.383)	5.99 (2.247)	5.76 (2.293)	
Median	6.00	6.00	6.00	5.64	
Min, Max	2.7, 10.0	0.9, 10.0	0.3, 10.0	0.2, 10.0	
C3D1 CFB					
n	13	25	54	92	
LS Mean (StdErr) [2]	-1.10 (0.539)	-1.18 (0.365)	-0.65 (0.211)	-1.06 (0.170)	
95% CI [2]	-2.19, -0.00	-1.92, -0.44	-1.07, -0.23	-1.39, -0.72	
Difference (95% CI) in CFB [2]		-0.08 (-1.34, 1.18)		-0.41 (-0.93, 0.11)	
p-value [3]		0.898		0.123	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	12	25	52	92	
Mean (StdDev)	5.69 (2.652)	5.77 (2.218)	5.86 (2.344)	5.45 (2.550)	
Median	4.93	5.57	6.04	5.58	
Min, Max	2.1, 9.7	1.8, 10.0	0.2, 10.0	0.0, 10.0	
C4D1 CFB					
n	12	25	52	92	
LS Mean (StdErr) [2]	-1.42 (0.612)	-1.35 (0.403)	-0.74 (0.268)	-1.36 (0.212)	
95% CI [2]	-2.67, -0.18	-2.17, -0.53	-1.26, -0.21	-1.78, -0.94	
Difference (95% CI) in CFB [2]		0.08 (-1.34, 1.50)		-0.63 (-1.28, 0.02)	
p-value [3]		0.915		0.059	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	26	51	93	
Mean (StdDev)	5.75 (2.596)	5.94 (2.306)	5.70 (2.406)	5.34 (2.483)	
Median	5.12	5.88	5.71	5.43	
Min, Max	2.0, 10.0	0.1, 10.0	0.6, 10.0	0.0, 10.0	
C5D1 CFB					
n	12	26	51	93	
LS Mean (StdErr) [2]	-1.26 (0.670)	-1.11 (0.430)	-0.96 (0.274)	-1.53 (0.213)	
95% CI [2]	-2.62, 0.10	-1.98, -0.23	-1.50, -0.42	-1.95, -1.11	
Difference (95% CI) in CFB [2]		0.15 (-1.41, 1.71)		-0.57 (-1.23, 0.09)	
p-value [3]		0.846		0.089	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	26	50	92	
Mean (StdDev)	5.65 (2.751)	5.69 (2.564)	5.83 (2.320)	5.06 (2.756)	
Median	4.89	5.11	6.00	5.19	
Min, Max	1.8, 10.0	0.0, 10.0	0.4, 10.0	0.0, 10.0	
C6D1 CFB					
n	12	26	50	92	
LS Mean (StdErr) [2]	-1.53 (0.733)	-1.42 (0.470)	-0.69 (0.292)	-1.68 (0.225)	
95% CI [2]	-3.02, -0.04	-2.37, -0.46	-1.27, -0.11	-2.13, -1.24	
Difference (95% CI) in CFB [2]		0.11 (-1.59, 1.82)		-0.99 (-1.70, -0.29)	
p-value [3]		0.895		0.006	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	12	25	50	90	
Mean (StdDev)	5.55 (2.886)	5.52 (2.542)	5.81 (2.416)	4.91 (2.656)	
Median	5.29	5.23	5.78	5.09	
Min, Max	1.5, 10.0	0.0, 10.0	0.2, 10.0	0.0, 10.0	
C7D1 CFB					
n	12	25	50	90	
LS Mean (StdErr) [2]	-1.62 (0.796)	-1.54 (0.517)	-0.73 (0.287)	-1.79 (0.223)	
95% CI [2]	-3.24, 0.00	-2.59, -0.48	-1.29, -0.16	-2.23, -1.34	
Difference (95% CI) in CFB [2]		0.08 (-1.79, 1.95)		-1.06 (-1.75, -0.36)	
Hedges'G (95% CI) in CFB		0.03 (-0.68, 0.75)		-0.50 (-0.87, -0.16)	
p-value [3]		0.929		0.003	
					0.194

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity					
	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	13	26	54	97	
Mean (StdDev)	4.22 (2.678)	4.11 (3.365)	3.59 (2.811)	3.92 (2.669)	
Median	2.86	4.49	3.15	3.86	
Min, Max	0.0, 8.5	0.0, 10.0	0.0, 9.3	0.0, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	54	94	
Mean (StdDev)	3.02 (2.438)	3.82 (3.041)	3.26 (2.751)	3.25 (2.563)	
Median	2.86	3.58	2.79	3.00	
Min, Max	0.0, 7.4	0.0, 10.0	0.0, 8.7	0.0, 10.0	
C2D1 CFB					
n	13	25	54	94	
LS Mean (StdErr) [2]	-0.98 (0.442)	-0.37 (0.300)	-0.30 (0.189)	-0.62 (0.151)	
95% CI [2]	-1.87, -0.08	-0.98, 0.24	-0.67, 0.07	-0.92, -0.32	
Difference (95% CI) in CFB [2]		0.61 (-0.43, 1.64)		-0.32 (-0.79, 0.14)	
p-value [3]		0.241		0.173	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	25	54	92	
Mean (StdDev)	2.60 (2.598)	3.49 (3.051)	2.95 (2.591)	2.82 (2.598)	
Median	1.85	2.93	2.29	2.16	
Min, Max	0.0, 7.6	0.0, 10.0	0.0, 8.1	0.0, 10.0	
C3D1 CFB					
n	13	25	54	92	
LS Mean (StdErr) [2]	-1.33 (0.547)	-0.67 (0.371)	-0.56 (0.216)	-0.98 (0.174)	
95% CI [2]	-2.44, -0.22	-1.42, 0.08	-0.99, -0.13	-1.32, -0.63	
Difference (95% CI) in CFB [2]		0.66 (-0.62, 1.94)		-0.41 (-0.95, 0.12)	
p-value [3]		0.302		0.127	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	12	25	52	92	
Mean (StdDev)	2.69 (2.154)	3.30 (2.956)	3.14 (2.764)	2.79 (2.694)	
Median	2.14	2.75	2.82	1.93	
Min, Max	0.0, 7.4	0.0, 10.0	0.0, 9.9	0.0, 10.0	
C4D1 CFB					
n	12	25	52	92	
LS Mean (StdErr) [2]	-1.15 (0.611)	-0.77 (0.402)	-0.35 (0.269)	-1.00 (0.213)	
95% CI [2]	-2.39, 0.09	-1.59, 0.05	-0.89, 0.18	-1.42, -0.57	
Difference (95% CI) in CFB [2]		0.38 (-1.04, 1.80)		-0.64 (-1.30, 0.01)	
p-value [3]		0.588		0.055	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	26	51	93	
Mean (StdDev)	2.44 (2.137)	3.30 (2.831)	3.21 (2.703)	2.57 (2.607)	
Median	2.14	3.01	2.57	1.80	
Min, Max	0.0, 6.5	0.0, 9.6	0.0, 9.6	0.0, 10.0	
C5D1 CFB					
n	12	26	51	93	
LS Mean (StdErr) [2]	-1.38 (0.703)	-0.63 (0.451)	-0.29 (0.249)	-1.19 (0.194)	
95% CI [2]	-2.81, 0.04	-1.54, 0.29	-0.78, 0.21	-1.57, -0.80	
Difference (95% CI) in CFB [2]		0.75 (-0.88, 2.39)		-0.90 (-1.50, -0.30)	
p-value [3]		0.355		0.004	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	26	50	92	
Mean (StdDev)	2.03 (2.007)	2.97 (2.755)	3.06 (2.700)	2.31 (2.505)	
Median	1.61	2.56	2.21	1.71	
Min, Max	0.0, 5.9	0.0, 9.7	0.0, 8.6	0.0, 10.0	
C6D1 CFB					
n	12	26	50	92	
LS Mean (StdErr) [2]	-1.67 (0.727)	-0.92 (0.467)	-0.41 (0.269)	-1.36 (0.207)	
95% CI [2]	-3.15, -0.20	-1.86, 0.03	-0.95, 0.12	-1.78, -0.95	
Difference (95% CI) in CFB [2]		0.76 (-0.94, 2.45)		-0.95 (-1.60, -0.30)	
p-value [3]		0.371		0.005	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	12	25	50	90	
Mean (StdDev)	2.44 (1.889)	2.72 (2.782)	2.97 (2.818)	2.40 (2.534)	
Median	2.11	2.11	1.89	1.63	
Min, Max	0.0, 5.9	0.0, 9.8	0.0, 10.0	0.0, 10.0	
C7D1 CFB					
n	12	25	50	90	
LS Mean (StdErr) [2]	-1.25 (0.748)	-1.08 (0.486)	-0.54 (0.287)	-1.28 (0.223)	
95% CI [2]	-2.77, 0.27	-2.07, -0.10	-1.11, 0.03	-1.72, -0.84	
Difference (95% CI) in CFB [2]		0.16 (-1.59, 1.92)		-0.74 (-1.43, -0.04)	
Hedges'G (95% CI) in CFB		0.06 (-0.65, 0.78)		-0.35 (-0.71, -0.01)	
p-value [3]		0.853		0.037	
					0.198

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	13	26	54	97	
Mean (StdDev)	6.35 (2.141)	5.89 (2.430)	4.96 (2.738)	5.61 (2.444)	
Median	6.85	5.92	5.22	5.86	
Min, Max	3.1, 10.0	0.3, 10.0	0.0, 10.0	0.0, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	54	94	
Mean (StdDev)	5.57 (2.221)	5.38 (2.553)	4.48 (2.703)	4.86 (2.725)	
Median	5.14	5.00	4.30	4.79	
Min, Max	3.0, 10.0	0.8, 10.0	0.0, 10.0	0.0, 10.0	
C2D1 CFB					
n	13	25	54	94	
LS Mean (StdErr) [2]	-0.80 (0.405)	-0.61 (0.274)	-0.45 (0.148)	-0.72 (0.118)	
95% CI [2]	-1.62, 0.02	-1.16, -0.05	-0.74, -0.16	-0.95, -0.48	
Difference (95% CI) in CFB [2]		0.19 (-0.75, 1.14)		-0.27 (-0.63, 0.10)	
p-value [3]		0.683		0.148	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	25	54	92	
Mean (StdDev)	5.36 (2.628)	5.06 (2.801)	4.28 (2.674)	4.50 (2.755)	
Median	5.00	5.00	4.15	4.48	
Min, Max	1.2, 10.0	0.2, 10.0	0.0, 10.0	0.0, 10.0	
C3D1 CFB					
n	13	25	54	92	
LS Mean (StdErr) [2]	-1.11 (0.500)	-0.97 (0.338)	-0.63 (0.183)	-1.07 (0.148)	
95% CI [2]	-2.12, -0.09	-1.65, -0.28	-0.99, -0.26	-1.36, -0.77	
Difference (95% CI) in CFB [2]		0.14 (-1.02, 1.31)		-0.44 (-0.89, 0.01)	
p-value [3]		0.807		0.056	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	12	25	52	92	
Mean (StdDev)	4.85 (2.381)	4.91 (2.796)	4.17 (2.833)	4.27 (2.879)	
Median	3.89	5.00	4.29	4.11	
Min, Max	2.4, 9.6	0.0, 10.0	0.0, 10.0	0.0, 10.0	
C4D1 CFB					
n	12	25	52	92	
LS Mean (StdErr) [2]	-1.36 (0.628)	-1.05 (0.414)	-0.77 (0.230)	-1.25 (0.183)	
95% CI [2]	-2.64, -0.09	-1.89, -0.21	-1.22, -0.31	-1.61, -0.89	
Difference (95% CI) in CFB [2]		0.31 (-1.14, 1.77)		-0.48 (-1.04, 0.08)	
p-value [3]		0.665		0.091	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	26	51	93	
Mean (StdDev)	4.80 (2.411)	5.04 (2.751)	3.91 (2.847)	4.18 (2.902)	
Median	3.75	4.96	3.79	4.54	
Min, Max	2.9, 10.0	0.0, 10.0	0.0, 10.0	0.0, 10.0	
C5D1 CFB					
n	12	26	51	93	
LS Mean (StdErr) [2]	-1.37 (0.691)	-0.82 (0.444)	-1.01 (0.252)	-1.35 (0.196)	
95% CI [2]	-2.77, 0.04	-1.72, 0.08	-1.51, -0.51	-1.73, -0.96	
Difference (95% CI) in CFB [2]		0.55 (-1.06, 2.16)		-0.34 (-0.94, 0.27)	
p-value [3]		0.492		0.274	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	26	50	92	
Mean (StdDev)	4.45 (2.396)	4.81 (2.778)	4.10 (2.804)	4.01 (2.974)	
Median	3.96	4.92	3.79	3.96	
Min, Max	1.8, 10.0	0.0, 10.0	0.0, 10.0	0.0, 10.0	
C6D1 CFB					
n	12	26	50	92	
LS Mean (StdErr) [2]	-1.62 (0.730)	-1.01 (0.469)	-0.66 (0.237)	-1.40 (0.183)	
95% CI [2]	-3.10, -0.13	-1.97, -0.06	-1.13, -0.19	-1.76, -1.04	
Difference (95% CI) in CFB [2]		0.60 (-1.09, 2.30)		-0.74 (-1.31, -0.16)	
p-value [3]		0.475		0.012	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	12	25	50	90	
Mean (StdDev)	4.46 (2.747)	4.72 (2.813)	4.13 (2.871)	3.95 (3.009)	
Median	3.89	5.00	3.68	4.04	
Min, Max	1.2, 10.0	0.0, 10.0	0.0, 10.0	0.0, 10.0	
C7D1 CFB					
n	12	25	50	90	
LS Mean (StdErr) [2]	-1.68 (0.791)	-1.06 (0.514)	-0.68 (0.243)	-1.47 (0.189)	
95% CI [2]	-3.29, -0.07	-2.11, -0.02	-1.16, -0.20	-1.84, -1.09	
Difference (95% CI) in CFB [2]		0.62 (-1.24, 2.47)		-0.78 (-1.37, -0.20)	
Hedges'G (95% CI) in CFB		0.23 (-0.47, 0.96)		-0.44 (-0.80, -0.10)	
p-value [3]		0.504		0.009	
					0.075

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	13	26	54	97	
Mean (StdDev)	5.16 (2.741)	4.53 (2.595)	4.03 (2.677)	4.27 (2.453)	
Median	5.50	4.37	4.36	4.00	
Min, Max	0.6, 8.9	0.2, 8.7	0.0, 9.9	0.0, 9.9	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	54	94	
Mean (StdDev)	4.36 (2.686)	3.90 (2.462)	3.82 (2.578)	3.67 (2.417)	
Median	4.21	3.57	3.82	3.52	
Min, Max	1.1, 8.1	0.2, 8.6	0.0, 9.1	0.0, 10.0	
C2D1 CFB					
n	13	25	54	94	
LS Mean (StdErr) [2]	-0.69 (0.450)	-0.61 (0.305)	-0.18 (0.166)	-0.53 (0.133)	
95% CI [2]	-1.60, 0.23	-1.23, 0.01	-0.51, 0.15	-0.79, -0.27	
Difference (95% CI) in CFB [2]		0.08 (-0.97, 1.13)		-0.36 (-0.76, 0.05)	
p-value [3]		0.882		0.087	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	25	54	92	
Mean (StdDev)	3.81 (2.777)	3.76 (2.426)	3.50 (2.534)	3.25 (2.382)	
Median	2.50	3.15	3.18	2.71	
Min, Max	0.9, 8.0	0.0, 7.7	0.0, 9.1	0.0, 10.0	
C3D1 CFB					
n	13	25	54	92	
LS Mean (StdErr) [2]	-1.33 (0.526)	-0.79 (0.356)	-0.45 (0.219)	-0.88 (0.177)	
95% CI [2]	-2.40, -0.26	-1.51, -0.06	-0.89, -0.02	-1.23, -0.53	
Difference (95% CI) in CFB [2]		0.54 (-0.69, 1.77)		-0.43 (-0.97, 0.11)	
p-value [3]		0.377		0.121	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	12	25	52	92	
Mean (StdDev)	3.50 (3.048)	3.29 (2.203)	3.65 (2.349)	3.19 (2.407)	
Median	2.82	3.29	3.43	2.69	
Min, Max	0.0, 8.4	0.0, 7.7	0.0, 8.2	0.0, 9.9	
C4D1 CFB					
n	12	25	52	92	
LS Mean (StdErr) [2]	-1.14 (0.618)	-1.10 (0.407)	-0.35 (0.244)	-0.90 (0.194)	
95% CI [2]	-2.40, 0.11	-1.93, -0.27	-0.83, 0.14	-1.28, -0.52	
Difference (95% CI) in CFB [2]		0.04 (-1.39, 1.48)		-0.56 (-1.15, 0.04)	
p-value [3]		0.954		0.067	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	26	51	93	
Mean (StdDev)	3.36 (2.661)	3.17 (2.181)	3.61 (2.456)	3.08 (2.400)	
Median	2.45	3.65	3.50	2.38	
Min, Max	0.0, 8.1	0.0, 7.9	0.0, 9.1	0.0, 10.0	
C5D1 CFB					
n	12	26	51	93	
LS Mean (StdErr) [2]	-1.35 (0.560)	-1.25 (0.359)	-0.47 (0.253)	-1.07 (0.196)	
95% CI [2]	-2.49, -0.22	-1.98, -0.52	-0.98, 0.03	-1.46, -0.68	
Difference (95% CI) in CFB [2]		0.10 (-1.20, 1.40)		-0.59 (-1.20, 0.02)	
p-value [3]		0.874		0.056	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	26	50	92	
Mean (StdDev)	2.94 (2.596)	3.03 (2.590)	3.36 (2.464)	2.78 (2.389)	
Median	2.49	2.33	2.88	2.07	
Min, Max	0.3, 7.6	0.0, 10.0	0.0, 8.9	0.0, 10.0	
C6D1 CFB					
n	12	26	50	92	
LS Mean (StdErr) [2]	-1.94 (0.666)	-1.45 (0.428)	-0.55 (0.249)	-1.30 (0.192)	
95% CI [2]	-3.29, -0.59	-2.32, -0.58	-1.04, -0.06	-1.68, -0.92	
Difference (95% CI) in CFB [2]		0.49 (-1.06, 2.04)		-0.76 (-1.36, -0.15)	
p-value [3]		0.524		0.014	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	12	25	50	90	
Mean (StdDev)	3.06 (2.689)	2.96 (2.488)	3.40 (2.617)	2.76 (2.372)	
Median	2.11	2.29	2.89	2.43	
Min, Max	0.0, 7.5	0.0, 9.6	0.0, 8.9	0.0, 10.0	
C7D1 CFB					
n	12	25	50	90	
LS Mean (StdErr) [2]	-1.87 (0.656)	-1.41 (0.426)	-0.56 (0.246)	-1.34 (0.191)	
95% CI [2]	-3.20, -0.54	-2.28, -0.54	-1.04, -0.07	-1.71, -0.96	
Difference (95% CI) in CFB [2]		0.46 (-1.08, 2.00)		-0.78 (-1.37, -0.18)	
Hedges'G (95% CI) in CFB		0.21 (-0.49, 0.94)		-0.43 (-0.79, -0.09)	
p-value [3]		0.546		0.011	
					0.104

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	13	26	54	97	
Mean (StdDev)	2.39 (2.348)	2.04 (2.681)	1.33 (1.154)	1.39 (1.321)	
Median	1.29	1.13	1.15	1.00	
Min, Max	0.2, 7.2	0.0, 12.2	0.0, 4.0	0.0, 5.4	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	54	94	
Mean (StdDev)	1.30 (1.601)	1.69 (2.209)	1.26 (1.220)	1.03 (1.183)	
Median	0.50	1.25	0.86	0.68	
Min, Max	0.0, 4.5	0.0, 10.7	0.0, 4.9	0.0, 5.1	
C2D1 CFB					
n	13	25	54	94	
LS Mean (StdErr) [2]	-1.00 (0.406)	-0.29 (0.275)	-0.08 (0.093)	-0.40 (0.074)	
95% CI [2]	-1.82, -0.17	-0.85, 0.26	-0.26, 0.10	-0.55, -0.25	
Difference (95% CI) in CFB [2]		0.70 (-0.24, 1.65)		-0.32 (-0.55, -0.09)	
p-value [3]		0.140		0.006	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	25	54	92	
Mean (StdDev)	1.20 (1.466)	1.30 (1.605)	1.17 (1.107)	0.97 (1.093)	
Median	0.50	0.86	0.82	0.65	
Min, Max	0.0, 3.9	0.0, 5.8	0.0, 4.4	0.0, 4.4	
C3D1 CFB					
n	13	25	54	92	
LS Mean (StdErr) [2]	-0.95 (0.547)	-0.62 (0.371)	-0.14 (0.123)	-0.40 (0.099)	
95% CI [2]	-2.06, 0.16	-1.37, 0.13	-0.38, 0.10	-0.60, -0.21	
Difference (95% CI) in CFB [2]		0.33 (-0.94, 1.61)		-0.27 (-0.57, 0.04)	
p-value [3]		0.600		0.083	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	12	25	52	92	
Mean (StdDev)	1.35 (1.550)	1.36 (1.896)	1.14 (1.044)	0.96 (1.267)	
Median	0.63	0.69	0.78	0.52	
Min, Max	0.0, 4.8	0.0, 9.0	0.0, 4.3	0.0, 6.2	
C4D1 CFB					
n	12	25	52	92	
LS Mean (StdErr) [2]	-0.92 (0.504)	-0.56 (0.332)	-0.19 (0.125)	-0.40 (0.099)	
95% CI [2]	-1.94, 0.11	-1.23, 0.12	-0.44, 0.06	-0.60, -0.20	
Difference (95% CI) in CFB [2]		0.36 (-0.81, 1.53)		-0.21 (-0.51, 0.10)	
p-value [3]		0.532		0.177	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	26	51	93	
Mean (StdDev)	1.21 (1.504)	1.25 (1.920)	1.14 (1.131)	0.97 (1.363)	
Median	0.46	0.62	0.79	0.46	
Min, Max	0.0, 4.8	0.0, 9.6	0.0, 4.0	0.0, 8.1	
C5D1 CFB					
n	12	26	51	93	
LS Mean (StdErr) [2]	-1.00 (0.483)	-0.68 (0.310)	-0.18 (0.157)	-0.40 (0.122)	
95% CI [2]	-1.98, -0.02	-1.31, -0.06	-0.49, 0.13	-0.65, -0.16	
Difference (95% CI) in CFB [2]		0.32 (-0.80, 1.44)		-0.22 (-0.60, 0.15)	
p-value [3]		0.568		0.243	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	26	50	92	
Mean (StdDev)	1.39 (1.936)	1.27 (1.871)	1.02 (1.102)	0.89 (1.115)	
Median	0.64	0.50	0.65	0.48	
Min, Max	0.0, 6.5	0.0, 9.0	0.0, 4.3	0.0, 5.3	
C6D1 CFB					
n	12	26	50	92	
LS Mean (StdErr) [2]	-0.89 (0.479)	-0.69 (0.308)	-0.22 (0.124)	-0.43 (0.096)	
95% CI [2]	-1.87, 0.08	-1.32, -0.07	-0.46, 0.03	-0.62, -0.24	
Difference (95% CI) in CFB [2]		0.20 (-0.92, 1.31)		-0.21 (-0.51, 0.09)	
p-value [3]		0.719		0.162	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	12	25	50	90	
Mean (StdDev)	1.39 (1.730)	1.04 (1.147)	1.00 (1.132)	0.83 (1.102)	
Median	0.57	0.44	0.52	0.29	
Min, Max	0.0, 5.9	0.0, 3.4	0.0, 4.1	0.0, 4.8	
C7D1 CFB					
n	12	25	50	90	
LS Mean (StdErr) [2]	-0.96 (0.489)	-0.55 (0.318)	-0.27 (0.140)	-0.57 (0.109)	
95% CI [2]	-1.95, 0.04	-1.19, 0.10	-0.54, 0.01	-0.79, -0.36	
Difference (95% CI) in CFB [2]		0.41 (-0.74, 1.56)		-0.31 (-0.65, 0.03)	
Hedges'G (95% CI) in CFB		0.25 (-0.45, 0.98)		-0.30 (-0.65, 0.05)	
p-value [3]		0.474		0.076	
					0.084

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	13	26	54	97	
Mean (StdDev)	3.88 (2.499)	3.05 (2.724)	3.02 (2.655)	3.06 (2.350)	
Median	3.07	2.32	2.04	2.50	
Min, Max	0.7, 8.1	0.0, 9.5	0.0, 9.5	0.0, 9.4	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	54	94	
Mean (StdDev)	2.28 (2.463)	3.06 (2.678)	2.52 (2.422)	2.21 (2.254)	
Median	1.36	2.54	2.01	1.45	
Min, Max	0.0, 7.3	0.0, 7.1	0.0, 9.1	0.0, 8.9	
C2D1 CFB					
n	13	25	54	94	
LS Mean (StdErr) [2]	-1.73 (0.494)	-0.04 (0.334)	-0.48 (0.180)	-0.85 (0.145)	
95% CI [2]	-2.73, -0.73	-0.72, 0.64	-0.84, -0.12	-1.14, -0.57	
Difference (95% CI) in CFB [2]		1.69 (0.54, 2.84)		-0.37 (-0.81, 0.07)	
p-value [3]		0.005		0.101	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	25	54	92	
Mean (StdDev)	2.17 (2.544)	2.58 (2.662)	2.38 (2.256)	2.06 (2.105)	
Median	0.86	1.69	1.58	1.36	
Min, Max	0.0, 7.4	0.0, 9.5	0.0, 8.7	0.0, 8.1	
C3D1 CFB					
n	13	25	54	92	
LS Mean (StdErr) [2]	-1.63 (0.595)	-0.44 (0.403)	-0.55 (0.231)	-0.88 (0.186)	
95% CI [2]	-2.84, -0.43	-1.26, 0.38	-1.01, -0.10	-1.25, -0.51	
Difference (95% CI) in CFB [2]		1.19 (-0.19, 2.58)		-0.33 (-0.90, 0.24)	
p-value [3]		0.089		0.258	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	12	25	52	92	
Mean (StdDev)	2.49 (2.395)	2.51 (2.455)	2.55 (2.376)	1.98 (2.275)	
Median	1.73	1.67	2.14	1.14	
Min, Max	0.0, 6.5	0.0, 7.5	0.0, 8.3	0.0, 8.9	
C4D1 CFB					
n	12	25	52	92	
LS Mean (StdErr) [2]	-1.49 (0.571)	-0.49 (0.376)	-0.44 (0.232)	-0.98 (0.184)	
95% CI [2]	-2.65, -0.33	-1.25, 0.27	-0.90, 0.02	-1.35, -0.62	
Difference (95% CI) in CFB [2]		1.00 (-0.33, 2.32)		-0.54 (-1.11, 0.02)	
p-value [3]		0.136		0.059	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	26	51	93	
Mean (StdDev)	2.09 (2.131)	2.30 (2.342)	2.55 (2.448)	1.92 (2.230)	
Median	1.14	1.48	2.09	1.08	
Min, Max	0.0, 6.2	0.0, 7.9	0.0, 8.5	0.0, 9.0	
C5D1 CFB					
n	12	26	51	93	
LS Mean (StdErr) [2]	-1.81 (0.654)	-0.69 (0.419)	-0.46 (0.260)	-1.05 (0.202)	
95% CI [2]	-3.13, -0.48	-1.54, 0.16	-0.97, 0.05	-1.45, -0.65	
Difference (95% CI) in CFB [2]		1.12 (-0.40, 2.64)		-0.59 (-1.22, 0.03)	
p-value [3]		0.144		0.064	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	26	50	92	
Mean (StdDev)	2.32 (2.329)	2.29 (2.513)	2.29 (2.403)	1.83 (2.149)	
Median	2.28	1.50	1.36	1.17	
Min, Max	0.0, 6.8	0.0, 8.9	0.0, 8.6	0.0, 8.6	
C6D1 CFB					
n	12	26	50	92	
LS Mean (StdErr) [2]	-1.59 (0.656)	-0.70 (0.421)	-0.51 (0.242)	-1.08 (0.187)	
95% CI [2]	-2.92, -0.26	-1.55, 0.15	-0.99, -0.03	-1.45, -0.71	
Difference (95% CI) in CFB [2]		0.89 (-0.64, 2.41)		-0.58 (-1.16, 0.01)	
p-value [3]		0.245		0.055	

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Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	12	25	50	90	
Mean (StdDev)	2.24 (2.125)	2.30 (2.538)	2.27 (2.572)	1.74 (2.176)	
Median	1.85	0.79	1.29	0.74	
Min, Max	0.0, 6.3	0.0, 8.7	0.0, 8.6	0.0, 8.4	
C7D1 CFB					
n	12	25	50	90	
LS Mean (StdErr) [2]	-1.73 (0.711)	-0.59 (0.462)	-0.61 (0.262)	-1.23 (0.204)	
95% CI [2]	-3.17, -0.28	-1.53, 0.35	-1.12, -0.09	-1.63, -0.83	
Difference (95% CI) in CFB [2]		1.14 (-0.53, 2.80)		-0.63 (-1.26, 0.01)	
Hedges'G (95% CI) in CFB		0.47 (-0.22, 1.22)		-0.33 (-0.68, 0.02)	
p-value [3]		0.175		0.053	
					0.026

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	63	114	4	9	
Mean (StdDev)	5.52 (2.460)	5.43 (2.357)	5.95 (1.817)	7.84 (1.871)	
Median	5.71	5.91	5.89	8.00	
Min, Max	0.0, 10.0	0.0, 10.0	4.1, 7.9	4.9, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	63	110	4	9	
Mean (StdDev)	4.86 (2.607)	4.68 (2.479)	6.09 (2.011)	6.99 (2.872)	
Median	5.21	4.35	6.00	7.29	
Min, Max	0.0, 10.0	0.0, 9.9	4.3, 8.1	1.7, 10.0	
C2D1 CFB					
n	63	110	4	9	
LS Mean (StdErr) [2]	-0.60 (0.177)	-0.72 (0.143)	0.55 (0.998)	-0.40 (0.791)	
95% CI [2]	-0.95, -0.26	-1.00, -0.43	-1.70, 2.81	-2.19, 1.39	
Difference (95% CI) in CFB [2]		-0.11 (-0.50, 0.28)		-0.96 (-2.90, 0.99)	
p-value [3]		0.574		0.296	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	63	108	4	9	
Mean (StdDev)	4.75 (2.676)	4.28 (2.546)	6.16 (2.003)	7.54 (2.517)	
Median	5.27	3.96	6.46	8.08	
Min, Max	0.0, 10.0	0.0, 10.0	3.6, 8.1	1.6, 10.0	
C3D1 CFB					
n	63	108	4	9	
LS Mean (StdErr) [2]	-0.70 (0.208)	-1.08 (0.169)	-0.27 (0.914)	-0.97 (0.724)	
95% CI [2]	-1.11, -0.29	-1.41, -0.74	-2.34, 1.79	-2.61, 0.67	
Difference (95% CI) in CFB [2]		-0.37 (-0.84, 0.09)		-0.70 (-2.48, 1.08)	
p-value [3]		0.112		0.399	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	60	108	4	9	
Mean (StdDev)	4.84 (2.759)	4.25 (2.657)	5.04 (2.770)	7.71 (2.489)	
Median	4.73	3.78	5.25	8.36	
Min, Max	0.0, 9.8	0.0, 10.0	2.1, 7.6	2.1, 10.0	
C4D1 CFB					
n	60	108	4	9	
LS Mean (StdErr) [2]	-0.59 (0.257)	-1.03 (0.203)	-1.56 (1.041)	-0.82 (0.825)	
95% CI [2]	-1.10, -0.08	-1.43, -0.62	-3.92, 0.79	-2.69, 1.05	
Difference (95% CI) in CFB [2]		-0.44 (-1.00, 0.13)		0.74 (-1.29, 2.77)	
p-value [3]		0.128		0.431	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	59	110	4	9	
Mean (StdDev)	4.83 (2.778)	3.97 (2.622)	5.10 (2.191)	7.70 (2.860)	
Median	4.86	3.73	4.75	8.00	
Min, Max	0.0, 9.8	0.0, 10.0	3.2, 7.7	1.8, 10.0	
C5D1 CFB					
n	59	110	4	9	
LS Mean (StdErr) [2]	-0.54 (0.271)	-1.22 (0.209)	-0.94 (1.332)	-0.42 (1.055)	
95% CI [2]	-1.07, -0.01	-1.63, -0.81	-3.95, 2.08	-2.80, 1.97	
Difference (95% CI) in CFB [2]		-0.68 (-1.27, -0.09)		0.52 (-2.08, 3.12)	
p-value [3]		0.025		0.661	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	58	109	4	9	
Mean (StdDev)	4.75 (2.732)	3.83 (2.562)	5.55 (2.584)	7.31 (2.961)	
Median	5.04	3.71	5.32	8.29	
Min, Max	0.0, 9.6	0.0, 10.0	3.0, 8.6	1.4, 10.0	
C6D1 CFB					
n	58	109	4	9	
LS Mean (StdErr) [2]	-0.46 (0.276)	-1.30 (0.213)	-0.42 (1.266)	-0.75 (1.003)	
95% CI [2]	-1.01, 0.08	-1.72, -0.88	-3.29, 2.44	-3.02, 1.52	
Difference (95% CI) in CFB [2]		-0.84 (-1.45, -0.23)		-0.33 (-2.80, 2.14)	
p-value [3]		0.007		0.772	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	59	106	3	9	
Mean (StdDev)	4.70 (2.739)	3.76 (2.609)	5.74 (2.374)	7.12 (3.372)	
Median	5.17	3.39	7.00	8.29	
Min, Max	0.0, 9.4	0.0, 10.0	3.0, 7.2	1.0, 10.0	
C7D1 CFB					
n	59	106	3	9	
LS Mean (StdErr) [2]	-0.58 (0.284)	-1.35 (0.223)	-0.64 (1.671)	-0.60 (1.216)	
95% CI [2]	-1.14, -0.02	-1.79, -0.91	-4.49, 3.21	-3.41, 2.20	
Difference (95% CI) in CFB [2]		-0.77 (-1.40, -0.14)		0.04 (-3.20, 3.27)	
Hedges'G (95% CI) in CFB		-0.34 (-0.67, -0.02)		0.01 (-1.47, 1.50)	
p-value [3]		0.016		0.980	
					0.491

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	63	114	4	9	
Mean (StdDev)	4.13 (2.415)	4.09 (2.169)	4.84 (2.663)	5.05 (2.354)	
Median	4.17	4.00	3.96	4.86	
Min, Max	0.0, 9.6	0.0, 9.8	2.7, 8.7	1.0, 9.6	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	63	110	4	9	
Mean (StdDev)	3.31 (2.223)	3.30 (2.161)	4.41 (1.240)	4.21 (2.048)	
Median	3.36	3.04	4.25	3.57	
Min, Max	0.0, 8.9	0.0, 9.4	3.1, 6.0	1.5, 7.9	
C2D1 CFB					
n	63	110	4	9	
LS Mean (StdErr) [2]	-0.76 (0.161)	-0.74 (0.130)	0.10 (1.030)	-0.22 (0.816)	
95% CI [2]	-1.07, -0.44	-0.99, -0.48	-2.23, 2.43	-2.07, 1.63	
Difference (95% CI) in CFB [2]		0.02 (-0.34, 0.38)		-0.32 (-2.33, 1.69)	
p-value [3]		0.918		0.725	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	63	108	4	9	
Mean (StdDev)	3.10 (2.264)	2.87 (2.126)	4.36 (1.126)	3.79 (2.749)	
Median	2.92	2.46	4.32	4.36	
Min, Max	0.0, 8.4	0.0, 8.3	3.3, 5.5	0.0, 8.3	
C3D1 CFB					
n	63	108	4	9	
LS Mean (StdErr) [2]	-0.92 (0.206)	-1.09 (0.167)	0.39 (1.147)	-0.49 (0.909)	
95% CI [2]	-1.32, -0.51	-1.42, -0.76	-2.21, 2.99	-2.55, 1.57	
Difference (95% CI) in CFB [2]		-0.17 (-0.63, 0.29)		-0.88 (-3.12, 1.36)	
p-value [3]		0.466		0.398	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	60	108	4	9	
Mean (StdDev)	3.08 (2.218)	2.61 (2.151)	4.30 (1.009)	3.50 (2.715)	
Median	3.04	2.20	4.14	4.07	
Min, Max	0.0, 7.9	0.0, 9.1	3.4, 5.6	0.0, 8.4	
C4D1 CFB					
n	60	108	4	9	
LS Mean (StdErr) [2]	-1.02 (0.249)	-1.37 (0.197)	0.09 (1.353)	-0.91 (1.072)	
95% CI [2]	-1.51, -0.53	-1.76, -0.98	-2.97, 3.15	-3.34, 1.51	
Difference (95% CI) in CFB [2]		-0.35 (-0.90, 0.19)		-1.00 (-3.64, 1.64)	
p-value [3]		0.203		0.412	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	59	110	4	9	
Mean (StdDev)	3.18 (2.244)	2.40 (2.071)	4.12 (1.133)	4.66 (3.668)	
Median	3.00	2.00	4.59	4.07	
Min, Max	0.0, 8.1	0.0, 8.0	2.4, 4.9	0.0, 9.4	
C5D1 CFB					
n	59	110	4	9	
LS Mean (StdErr) [2]	-0.89 (0.265)	-1.53 (0.204)	1.22 (1.808)	1.18 (1.433)	
95% CI [2]	-1.42, -0.37	-1.93, -1.13	-2.87, 5.31	-2.06, 4.42	
Difference (95% CI) in CFB [2]		-0.64 (-1.22, -0.06)		-0.04 (-3.57, 3.49)	
p-value [3]		0.032		0.981	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	58	109	4	9	
Mean (StdDev)	2.61 (2.125)	2.31 (2.188)	4.11 (0.792)	3.93 (2.830)	
Median	2.35	1.71	3.96	3.21	
Min, Max	0.0, 7.1	0.0, 9.6	3.4, 5.1	0.0, 8.9	
C6D1 CFB					
n	58	109	4	9	
LS Mean (StdErr) [2]	-1.29 (0.279)	-1.59 (0.215)	1.06 (1.265)	0.63 (1.002)	
95% CI [2]	-1.84, -0.74	-2.02, -1.17	-1.80, 3.92	-1.64, 2.90	
Difference (95% CI) in CFB [2]		-0.31 (-0.92, 0.31)		-0.43 (-2.90, 2.04)	
p-value [3]		0.328		0.703	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	59	106	3	9	
Mean (StdDev)	2.83 (2.340)	2.40 (2.180)	4.05 (1.358)	3.19 (2.757)	
Median	2.43	2.00	4.00	2.57	
Min, Max	0.0, 8.3	0.0, 9.4	2.7, 5.4	0.0, 8.4	
C7D1 CFB					
n	59	106	3	9	
LS Mean (StdErr) [2]	-1.18 (0.273)	-1.53 (0.214)	1.06 (1.400)	-0.01 (1.018)	
95% CI [2]	-1.72, -0.64	-1.95, -1.10	-2.16, 4.29	-2.35, 2.34	
Difference (95% CI) in CFB [2]		-0.35 (-0.95, 0.26)		-1.07 (-3.78, 1.64)	
Hedges'G (95% CI) in CFB		-0.16 (-0.48, 0.16)		-0.34 (-1.92, 1.07)	
p-value [3]		0.259		0.389	
					0.741

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	63	114	4	9	
Mean (StdDev)	3.52 (2.477)	3.20 (2.478)	3.73 (2.667)	3.39 (3.175)	
Median	3.14	2.81	3.39	3.92	
Min, Max	0.0, 8.9	0.0, 8.9	0.9, 7.2	0.0, 9.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	63	110	4	9	
Mean (StdDev)	2.95 (2.401)	2.70 (2.334)	3.61 (1.666)	3.12 (2.766)	
Median	2.42	2.29	3.39	3.50	
Min, Max	0.0, 8.3	0.0, 8.8	1.9, 5.8	0.0, 7.7	
C2D1 CFB					
n	63	110	4	9	
LS Mean (StdErr) [2]	-0.48 (0.175)	-0.41 (0.142)	0.27 (1.042)	0.02 (0.826)	
95% CI [2]	-0.83, -0.14	-0.69, -0.13	-2.09, 2.62	-1.85, 1.89	
Difference (95% CI) in CFB [2]		0.08 (-0.31, 0.47)		-0.25 (-2.28, 1.78)	
p-value [3]		0.696		0.788	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	63	108	4	9	
Mean (StdDev)	2.58 (2.337)	2.37 (2.260)	3.73 (1.448)	3.09 (2.595)	
Median	2.00	1.86	3.18	3.36	
Min, Max	0.0, 7.7	0.0, 8.9	2.7, 5.9	0.0, 6.8	
C3D1 CFB					
n	63	108	4	9	
LS Mean (StdErr) [2]	-0.86 (0.208)	-0.72 (0.169)	0.02 (1.306)	-0.43 (1.035)	
95% CI [2]	-1.27, -0.45	-1.05, -0.38	-2.94, 2.97	-2.77, 1.92	
Difference (95% CI) in CFB [2]		0.14 (-0.32, 0.61)		-0.45 (-2.99, 2.10)	
p-value [3]		0.546		0.702	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	60	108	4	9	
Mean (StdDev)	2.73 (2.281)	2.15 (2.259)	2.82 (1.434)	2.21 (2.233)	
Median	2.04	1.52	3.11	1.62	
Min, Max	0.0, 7.4	0.0, 9.2	0.9, 4.2	0.0, 6.0	
C4D1 CFB					
n	60	108	4	9	
LS Mean (StdErr) [2]	-0.86 (0.242)	-1.01 (0.192)	-0.37 (1.583)	-0.61 (1.254)	
95% CI [2]	-1.33, -0.38	-1.39, -0.63	-3.95, 3.21	-3.45, 2.23	
Difference (95% CI) in CFB [2]		-0.15 (-0.68, 0.38)		-0.24 (-3.32, 2.85)	
p-value [3]		0.574		0.867	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	59	110	4	9	
Mean (StdDev)	2.78 (2.280)	2.03 (2.151)	3.02 (0.602)	3.28 (3.165)	
Median	2.57	1.44	2.89	2.43	
Min, Max	0.0, 8.5	0.0, 8.9	2.4, 3.9	0.0, 7.6	
C5D1 CFB					
n	59	110	4	9	
LS Mean (StdErr) [2]	-0.80 (0.246)	-1.07 (0.190)	1.31 (2.284)	1.25 (1.810)	
95% CI [2]	-1.28, -0.31	-1.44, -0.69	-3.86, 6.48	-2.85, 5.34	
Difference (95% CI) in CFB [2]		-0.27 (-0.81, 0.27)		-0.06 (-4.52, 4.40)	
p-value [3]		0.321		0.976	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	58	109	4	9	
Mean (StdDev)	2.38 (2.155)	1.83 (2.109)	3.48 (0.718)	2.75 (2.962)	
Median	1.93	1.38	3.64	1.60	
Min, Max	0.0, 7.9	0.0, 9.9	2.5, 4.1	0.0, 8.4	
C6D1 CFB					
n	58	109	4	9	
LS Mean (StdErr) [2]	-1.16 (0.261)	-1.26 (0.201)	1.21 (1.499)	0.55 (1.188)	
95% CI [2]	-1.67, -0.64	-1.66, -0.87	-2.18, 4.60	-2.14, 3.23	
Difference (95% CI) in CFB [2]		-0.11 (-0.68, 0.47)		-0.66 (-3.59, 2.26)	
p-value [3]		0.716		0.620	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	59	106	3	9	
Mean (StdDev)	2.52 (2.314)	1.90 (2.176)	3.43 (0.610)	2.42 (2.337)	
Median	1.79	1.25	3.50	1.57	
Min, Max	0.0, 7.7	0.0, 9.5	2.8, 4.0	0.0, 7.1	
C7D1 CFB					
n	59	106	3	9	
LS Mean (StdErr) [2]	-1.04 (0.281)	-1.16 (0.220)	1.36 (2.027)	0.33 (1.475)	
95% CI [2]	-1.59, -0.48	-1.59, -0.73	-3.31, 6.03	-3.07, 3.73	
Difference (95% CI) in CFB [2]		-0.12 (-0.74, 0.50)		-1.03 (-4.95, 2.90)	
Hedges'G (95% CI) in CFB		-0.06 (-0.38, 0.26)		-0.22 (-1.77, 1.21)	
p-value [3]		0.694		0.563	
					0.704

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	63	114	4	9	
Mean (StdDev)	6.17 (2.895)	5.49 (3.031)	3.88 (4.516)	6.27 (2.883)	
Median	7.00	5.86	2.75	6.86	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 10.0	0.0, 9.4	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	63	110	4	9	
Mean (StdDev)	5.76 (2.814)	4.59 (2.755)	3.59 (3.213)	5.32 (2.881)	
Median	6.07	4.74	3.71	5.57	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 6.9	0.0, 9.2	
C2D1 CFB					
n	63	110	4	9	
LS Mean (StdErr) [2]	-0.37 (0.167)	-0.87 (0.135)	0.37 (1.388)	-0.16 (1.100)	
95% CI [2]	-0.70, -0.03	-1.14, -0.60	-2.77, 3.51	-2.65, 2.33	
Difference (95% CI) in CFB [2]		-0.50 (-0.87, -0.13)		-0.53 (-3.24, 2.18)	
p-value [3]		0.008		0.669	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	63	108	4	9	
Mean (StdDev)	5.74 (2.880)	4.16 (2.591)	3.02 (2.441)	4.91 (2.828)	
Median	5.67	4.00	3.32	5.57	
Min, Max	0.0, 10.0	0.0, 9.8	0.0, 5.4	0.0, 9.0	
C3D1 CFB					
n	63	108	4	9	
LS Mean (StdErr) [2]	-0.28 (0.212)	-1.23 (0.172)	0.10 (1.362)	-0.19 (1.079)	
95% CI [2]	-0.70, 0.14	-1.57, -0.89	-2.98, 3.18	-2.63, 2.25	
Difference (95% CI) in CFB [2]		-0.95 (-1.42, -0.48)		-0.29 (-2.94, 2.37)	
p-value [3]		<0.001		0.813	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	60	108	4	9	
Mean (StdDev)	5.66 (2.895)	3.95 (2.579)	3.02 (2.451)	4.50 (2.909)	
Median	5.96	3.78	3.18	4.93	
Min, Max	0.0, 10.0	0.0, 9.3	0.0, 5.7	0.0, 9.4	
C4D1 CFB					
n	60	108	4	9	
LS Mean (StdErr) [2]	-0.20 (0.219)	-1.33 (0.173)	0.36 (1.859)	-0.33 (1.473)	
95% CI [2]	-0.63, 0.23	-1.67, -0.99	-3.84, 4.56	-3.66, 3.00	
Difference (95% CI) in CFB [2]		-1.13 (-1.61, -0.65)		-0.69 (-4.31, 2.94)	
p-value [3]		<0.0001		0.678	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	59	110	4	9	
Mean (StdDev)	5.60 (2.872)	3.73 (2.536)	2.44 (1.857)	4.12 (3.125)	
Median	5.21	3.28	2.92	3.07	
Min, Max	0.0, 10.0	0.0, 9.9	0.0, 3.9	0.1, 9.3	
C5D1 CFB					
n	59	110	4	9	
LS Mean (StdErr) [2]	-0.31 (0.238)	-1.57 (0.183)	0.12 (1.945)	-0.37 (1.541)	
95% CI [2]	-0.78, 0.16	-1.93, -1.20	-4.28, 4.52	-3.86, 3.11	
Difference (95% CI) in CFB [2]		-1.26 (-1.78, -0.74)		-0.49 (-4.28, 3.31)	
p-value [3]		<0.0001		0.777	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	58	109	4	9	
Mean (StdDev)	5.68 (2.875)	3.60 (2.543)	2.54 (1.890)	3.58 (3.148)	
Median	5.26	3.29	2.86	3.07	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 4.4	0.3, 10.0	
C6D1 CFB					
n	58	109	4	9	
LS Mean (StdErr) [2]	-0.20 (0.284)	-1.62 (0.219)	0.62 (1.723)	-0.46 (1.366)	
95% CI [2]	-0.76, 0.36	-2.05, -1.19	-3.27, 4.52	-3.54, 2.63	
Difference (95% CI) in CFB [2]		-1.42 (-2.04, -0.79)		-1.08 (-4.44, 2.28)	
p-value [3]		<0.0001		0.486	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	59	106	3	9	
Mean (StdDev)	5.60 (2.884)	3.56 (2.620)	3.76 (1.286)	3.57 (3.323)	
Median	5.36	3.23	3.71	2.79	
Min, Max	0.0, 10.0	0.0, 10.0	2.5, 5.1	0.0, 10.0	
C7D1 CFB					
n	59	106	3	9	
LS Mean (StdErr) [2]	-0.32 (0.287)	-1.70 (0.225)	0.80 (2.398)	-0.63 (1.745)	
95% CI [2]	-0.89, 0.24	-2.14, -1.26	-4.73, 6.33	-4.66, 3.39	
Difference (95% CI) in CFB [2]		-1.38 (-2.01, -0.74)		-1.43 (-6.08, 3.21)	
Hedges'G (95% CI) in CFB		-0.60 (-0.94, -0.28)		-0.26 (-1.82, 1.16)	
p-value [3]		<0.0001		0.497	
					0.923

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	63	114	4	9	
Mean (StdDev)	6.10 (2.484)	5.33 (2.640)	3.93 (4.490)	7.06 (2.773)	
Median	6.57	5.35	2.86	7.36	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 10.0	1.7, 9.8	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	63	110	4	9	
Mean (StdDev)	5.38 (2.689)	4.26 (2.289)	3.75 (3.495)	5.65 (3.056)	
Median	5.75	4.26	3.96	5.86	
Min, Max	0.0, 10.0	0.0, 9.9	0.0, 7.1	0.5, 9.4	
C2D1 CFB					
n	63	110	4	9	
LS Mean (StdErr) [2]	-0.78 (0.222)	-1.14 (0.179)	0.20 (1.391)	-1.09 (1.102)	
95% CI [2]	-1.21, -0.34	-1.49, -0.78	-2.95, 3.35	-3.59, 1.40	
Difference (95% CI) in CFB [2]		-0.36 (-0.85, 0.13)		-1.29 (-4.01, 1.42)	
p-value [3]		0.149		0.309	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	63	108	4	9	
Mean (StdDev)	5.14 (2.703)	3.54 (2.287)	2.86 (2.729)	5.39 (3.588)	
Median	4.85	3.46	2.96	6.86	
Min, Max	0.0, 10.0	0.0, 8.6	0.0, 5.5	0.1, 9.7	
C3D1 CFB					
n	63	108	4	9	
LS Mean (StdErr) [2]	-0.86 (0.270)	-1.69 (0.218)	-0.03 (1.811)	-0.73 (1.435)	
95% CI [2]	-1.39, -0.32	-2.12, -1.26	-4.12, 4.07	-3.98, 2.51	
Difference (95% CI) in CFB [2]		-0.83 (-1.43, -0.23)		-0.71 (-4.24, 2.83)	
p-value [3]		0.007		0.662	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	60	108	4	9	
Mean (StdDev)	5.05 (2.776)	3.30 (2.431)	2.84 (2.661)	5.07 (3.385)	
Median	5.22	3.18	2.79	5.93	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 5.8	1.3, 9.3	
C4D1 CFB					
n	60	108	4	9	
LS Mean (StdErr) [2]	-1.05 (0.322)	-1.98 (0.255)	0.02 (2.174)	-0.66 (1.723)	
95% CI [2]	-1.68, -0.41	-2.49, -1.48	-4.90, 4.94	-4.56, 3.24	
Difference (95% CI) in CFB [2]		-0.93 (-1.64, -0.23)		-0.68 (-4.92, 3.57)	
p-value [3]		0.010		0.727	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	59	110	4	9	
Mean (StdDev)	5.19 (2.608)	3.07 (2.381)	2.53 (2.315)	4.61 (3.701)	
Median	5.14	2.93	2.71	3.86	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 4.7	0.0, 9.3	
C5D1 CFB					
n	59	110	4	9	
LS Mean (StdErr) [2]	-0.86 (0.336)	-2.11 (0.259)	-0.05 (2.112)	-0.98 (1.673)	
95% CI [2]	-1.52, -0.20	-2.62, -1.59	-4.83, 4.72	-4.77, 2.80	
Difference (95% CI) in CFB [2]		-1.24 (-1.98, -0.51)		-0.93 (-5.05, 3.19)	
p-value [3]		0.001		0.621	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	58	109	4	9	
Mean (StdDev)	5.10 (2.632)	2.99 (2.425)	2.52 (2.271)	4.56 (3.556)	
Median	5.00	2.75	2.50	2.93	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 5.1	0.4, 10.0	
C6D1 CFB					
n	58	109	4	9	
LS Mean (StdErr) [2]	-1.00 (0.347)	-2.27 (0.267)	0.02 (1.715)	-0.91 (1.359)	
95% CI [2]	-1.69, -0.32	-2.80, -1.75	-3.86, 3.90	-3.98, 2.17	
Difference (95% CI) in CFB [2]		-1.27 (-2.04, -0.51)		-0.92 (-4.27, 2.42)	
p-value [3]		0.001		0.548	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	59	106	3	9	
Mean (StdDev)	5.12 (2.574)	2.91 (2.361)	3.76 (1.967)	4.64 (3.634)	
Median	5.07	2.70	4.71	3.00	
Min, Max	0.0, 10.0	0.0, 10.0	1.5, 5.1	0.3, 10.0	
C7D1 CFB					
n	59	106	3	9	
LS Mean (StdErr) [2]	-0.98 (0.359)	-2.33 (0.282)	0.19 (2.287)	-0.89 (1.664)	
95% CI [2]	-1.68, -0.27	-2.88, -1.77	-5.09, 5.46	-4.73, 2.95	
Difference (95% CI) in CFB [2]		-1.35 (-2.15, -0.56)		-1.08 (-5.51, 3.35)	
Hedges'G (95% CI) in CFB		-0.47 (-0.80, -0.15)		-0.21 (-1.75, 1.23)	
p-value [3]		<0.001		0.590	
					0.749

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	63	114	4	9	
Mean (StdDev)	6.03 (2.516)	5.38 (2.352)	4.46 (3.045)	5.49 (3.212)	
Median	5.92	5.46	5.50	5.29	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 6.9	0.0, 9.7	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	63	110	4	9	
Mean (StdDev)	5.47 (2.620)	4.70 (2.383)	4.05 (2.844)	4.47 (3.448)	
Median	5.08	4.78	4.82	5.07	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 6.6	0.0, 9.9	
C2D1 CFB					
n	63	110	4	9	
LS Mean (StdErr) [2]	-0.57 (0.209)	-0.72 (0.169)	0.28 (0.862)	-0.31 (0.683)	
95% CI [2]	-0.99, -0.16	-1.05, -0.39	-1.67, 2.23	-1.85, 1.24	
Difference (95% CI) in CFB [2]		-0.14 (-0.61, 0.32)		-0.58 (-2.26, 1.10)	
p-value [3]		0.539		0.453	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	63	108	4	9	
Mean (StdDev)	5.25 (2.792)	4.11 (2.427)	4.36 (3.115)	4.60 (3.462)	
Median	5.25	4.12	5.04	5.15	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 7.4	0.6, 10.0	
C3D1 CFB					
n	63	108	4	9	
LS Mean (StdErr) [2]	-0.69 (0.251)	-1.23 (0.203)	0.71 (1.149)	-0.03 (0.910)	
95% CI [2]	-1.19, -0.20	-1.63, -0.83	-1.89, 3.31	-2.09, 2.03	
Difference (95% CI) in CFB [2]		-0.54 (-1.10, 0.02)		-0.74 (-2.98, 1.50)	
p-value [3]		0.057		0.475	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	60	108	4	9	
Mean (StdDev)	5.24 (2.848)	3.87 (2.461)	3.96 (3.003)	4.53 (3.317)	
Median	5.36	3.68	4.29	4.00	
Min, Max	0.1, 10.0	0.0, 10.0	0.0, 7.3	1.0, 9.9	
C4D1 CFB					
n	60	108	4	9	
LS Mean (StdErr) [2]	-0.81 (0.287)	-1.56 (0.227)	0.32 (1.555)	0.23 (1.232)	
95% CI [2]	-1.38, -0.24	-2.01, -1.11	-3.20, 3.84	-2.56, 3.01	
Difference (95% CI) in CFB [2]		-0.75 (-1.38, -0.12)		-0.09 (-3.13, 2.94)	
p-value [3]		0.020		0.946	

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Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	59	110	4	9	
Mean (StdDev)	5.29 (2.842)	3.62 (2.445)	3.86 (2.888)	5.09 (3.404)	
Median	5.46	3.75	4.21	4.57	
Min, Max	0.0, 10.0	0.0, 9.7	0.0, 7.0	0.3, 9.8	
C5D1 CFB					
n	59	110	4	9	
LS Mean (StdErr) [2]	-0.79 (0.316)	-1.81 (0.244)	1.21 (1.652)	1.37 (1.309)	
95% CI [2]	-1.42, -0.17	-2.29, -1.33	-2.53, 4.95	-1.59, 4.34	
Difference (95% CI) in CFB [2]		-1.02 (-1.71, -0.32)		0.16 (-3.06, 3.39)	
p-value [3]		0.004		0.912	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

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[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	58	109	4	9	
Mean (StdDev)	5.15 (2.881)	3.52 (2.499)	3.61 (2.866)	4.47 (3.480)	
Median	5.14	3.50	3.71	3.00	
Min, Max	0.0, 10.0	0.0, 9.8	0.0, 7.0	0.1, 10.0	
C6D1 CFB					
n	58	109	4	9	
LS Mean (StdErr) [2]	-0.98 (0.334)	-1.93 (0.257)	0.94 (1.344)	0.79 (1.065)	
95% CI [2]	-1.64, -0.32	-2.44, -1.42	-2.10, 3.98	-1.62, 3.20	
Difference (95% CI) in CFB [2]		-0.95 (-1.68, -0.21)		-0.15 (-2.77, 2.47)	
p-value [3]		0.012		0.899	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	59	106	3	9	
Mean (StdDev)	5.15 (2.874)	3.27 (2.438)	4.60 (1.985)	4.41 (3.633)	
Median	5.36	3.04	3.79	3.71	
Min, Max	0.0, 10.0	0.0, 9.6	3.1, 6.9	0.0, 10.0	
C7D1 CFB					
n	59	106	3	9	
LS Mean (StdErr) [2]	-0.89 (0.344)	-2.04 (0.270)	0.40 (1.540)	0.43 (1.121)	
95% CI [2]	-1.57, -0.21	-2.58, -1.51	-3.15, 3.95	-2.16, 3.01	
Difference (95% CI) in CFB [2]		-1.15 (-1.91, -0.39)		0.03 (-2.95, 3.01)	
Hedges'G (95% CI) in CFB		-0.42 (-0.75, -0.10)		0.01 (-1.47, 1.50)	
p-value [3]		0.003		0.982	
					0.353

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	63	114	4	9	
Mean (StdDev)	6.72 (1.974)	6.89 (1.989)	7.80 (2.484)	7.64 (1.922)	
Median	6.64	7.11	8.39	7.43	
Min, Max	0.0, 10.0	0.1, 10.0	4.4, 10.0	4.2, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	63	110	4	9	
Mean (StdDev)	6.32 (1.950)	6.16 (2.201)	7.23 (1.586)	7.53 (1.890)	
Median	6.29	6.25	7.96	7.29	
Min, Max	2.3, 10.0	0.1, 10.0	4.9, 8.1	4.6, 10.0	
C2D1 CFB					
n	63	110	4	9	
LS Mean (StdErr) [2]	-0.42 (0.173)	-0.76 (0.140)	-0.65 (0.826)	-0.06 (0.655)	
95% CI [2]	-0.76, -0.08	-1.04, -0.48	-2.52, 1.21	-1.54, 1.42	
Difference (95% CI) in CFB [2]		-0.34 (-0.72, 0.04)		0.59 (-1.02, 2.21)	
p-value [3]		0.082		0.426	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	63	108	4	9	
Mean (StdDev)	5.97 (2.261)	5.70 (2.295)	7.09 (2.305)	7.27 (2.013)	
Median	6.00	5.64	7.89	7.57	
Min, Max	0.3, 10.0	0.2, 10.0	3.7, 8.9	3.1, 10.0	
C3D1 CFB					
n	63	108	4	9	
LS Mean (StdErr) [2]	-0.74 (0.223)	-1.17 (0.180)	-0.96 (1.158)	-0.61 (0.917)	
95% CI [2]	-1.18, -0.31	-1.53, -0.81	-3.58, 1.66	-2.68, 1.47	
Difference (95% CI) in CFB [2]		-0.43 (-0.92, 0.07)		0.35 (-1.91, 2.61)	
p-value [3]		0.091		0.733	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	60	108	4	9	
Mean (StdDev)	5.76 (2.404)	5.39 (2.457)	6.93 (1.994)	7.09 (2.286)	
Median	5.88	5.38	7.25	7.71	
Min, Max	0.2, 10.0	0.0, 10.0	4.3, 8.9	2.2, 10.0	
C4D1 CFB					
n	60	108	4	9	
LS Mean (StdErr) [2]	-0.93 (0.273)	-1.48 (0.216)	-1.14 (1.638)	-0.78 (1.298)	
95% CI [2]	-1.47, -0.39	-1.91, -1.05	-4.84, 2.57	-3.71, 2.16	
Difference (95% CI) in CFB [2]		-0.55 (-1.15, 0.05)		0.36 (-2.83, 3.56)	
p-value [3]		0.070		0.803	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	59	110	4	9	
Mean (StdDev)	5.68 (2.463)	5.34 (2.387)	6.22 (1.889)	7.15 (2.706)	
Median	5.57	5.41	6.25	7.50	
Min, Max	0.6, 10.0	0.0, 10.0	3.9, 8.5	1.9, 10.0	
C5D1 CFB					
n	59	110	4	9	
LS Mean (StdErr) [2]	-0.95 (0.279)	-1.47 (0.216)	-1.81 (1.979)	-0.79 (1.568)	
95% CI [2]	-1.50, -0.40	-1.89, -1.04	-6.28, 2.67	-4.34, 2.75	
Difference (95% CI) in CFB [2]		-0.52 (-1.13, 0.10)		1.01 (-2.85, 4.87)	
p-value [3]		0.098		0.567	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	58	109	4	9	
Mean (StdDev)	5.74 (2.427)	5.06 (2.683)	6.57 (1.719)	6.92 (2.668)	
Median	5.80	5.10	6.61	7.50	
Min, Max	0.4, 10.0	0.0, 10.0	4.5, 8.6	1.0, 10.0	
C6D1 CFB					
n	58	109	4	9	
LS Mean (StdErr) [2]	-0.81 (0.303)	-1.70 (0.234)	-1.49 (1.774)	-1.03 (1.406)	
95% CI [2]	-1.41, -0.21	-2.16, -1.23	-5.50, 2.52	-4.21, 2.15	
Difference (95% CI) in CFB [2]		-0.89 (-1.56, -0.22)		0.46 (-3.01, 3.92)	
p-value [3]		0.010		0.772	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	59	106	3	9	
Mean (StdDev)	5.70 (2.519)	4.94 (2.589)	6.86 (1.777)	6.25 (2.998)	
Median	5.64	5.09	7.21	6.86	
Min, Max	0.2, 10.0	0.0, 10.0	4.9, 8.4	1.4, 10.0	
C7D1 CFB					
n	59	106	3	9	
LS Mean (StdErr) [2]	-0.85 (0.307)	-1.79 (0.240)	-1.59 (1.901)	-0.94 (1.383)	
95% CI [2]	-1.46, -0.24	-2.27, -1.32	-5.97, 2.80	-4.13, 2.25	
Difference (95% CI) in CFB [2]		-0.94 (-1.62, -0.27)		0.65 (-3.04, 4.33)	
Hedges'G (95% CI) in CFB		-0.39 (-0.72, -0.07)		0.15 (-1.30, 1.67)	
p-value [3]		0.007		0.696	
					0.238

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	63	114	4	9	
Mean (StdDev)	3.73 (2.743)	3.90 (2.840)	3.50 (3.744)	4.72 (2.518)	
Median	3.07	3.85	2.79	4.50	
Min, Max	0.0, 9.3	0.0, 10.0	0.0, 8.4	0.7, 9.8	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	63	110	4	9	
Mean (StdDev)	3.21 (2.701)	3.27 (2.620)	3.23 (2.629)	4.59 (3.085)	
Median	2.79	3.00	3.25	5.07	
Min, Max	0.0, 8.7	0.0, 10.0	0.0, 6.4	0.0, 10.0	
C2D1 CFB					
n	63	110	4	9	
LS Mean (StdErr) [2]	-0.47 (0.195)	-0.62 (0.158)	-0.01 (1.129)	-0.07 (0.895)	
95% CI [2]	-0.86, -0.09	-0.94, -0.31	-2.56, 2.55	-2.10, 1.95	
Difference (95% CI) in CFB [2]		-0.15 (-0.58, 0.28)		-0.07 (-2.27, 2.14)	
p-value [3]		0.494		0.946	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	63	108	4	9	
Mean (StdDev)	2.85 (2.609)	2.89 (2.643)	3.38 (2.229)	3.91 (3.351)	
Median	2.07	2.16	3.75	4.07	
Min, Max	0.0, 8.1	0.0, 10.0	0.4, 5.6	0.0, 10.0	
C3D1 CFB					
n	63	108	4	9	
LS Mean (StdErr) [2]	-0.78 (0.226)	-0.95 (0.183)	0.62 (1.464)	-0.17 (1.160)	
95% CI [2]	-1.22, -0.33	-1.31, -0.59	-2.69, 3.93	-2.79, 2.46	
Difference (95% CI) in CFB [2]		-0.17 (-0.68, 0.33)		-0.79 (-3.64, 2.07)	
p-value [3]		0.497		0.549	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	60	108	4	9	
Mean (StdDev)	3.05 (2.696)	2.80 (2.705)	3.02 (2.122)	4.03 (3.159)	
Median	2.50	2.04	3.75	3.93	
Min, Max	0.0, 9.9	0.0, 10.0	0.0, 4.6	0.0, 10.0	
C4D1 CFB					
n	60	108	4	9	
LS Mean (StdErr) [2]	-0.59 (0.279)	-1.04 (0.221)	-0.06 (1.496)	-0.25 (1.185)	
95% CI [2]	-1.14, -0.04	-1.47, -0.60	-3.45, 3.32	-2.93, 2.44	
Difference (95% CI) in CFB [2]		-0.45 (-1.06, 0.16)		-0.19 (-3.10, 2.73)	
p-value [3]		0.150		0.889	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	59	110	4	9	
Mean (StdDev)	3.05 (2.670)	2.60 (2.559)	3.24 (1.583)	4.29 (3.521)	
Median	2.36	1.93	3.29	3.62	
Min, Max	0.0, 9.6	0.0, 9.6	1.5, 4.9	0.0, 10.0	
C5D1 CFB					
n	59	110	4	9	
LS Mean (StdErr) [2]	-0.54 (0.267)	-1.14 (0.206)	1.73 (1.558)	1.02 (1.235)	
95% CI [2]	-1.07, -0.02	-1.55, -0.73	-1.80, 5.25	-1.77, 3.81	
Difference (95% CI) in CFB [2]		-0.60 (-1.18, -0.01)		-0.71 (-3.75, 2.33)	
p-value [3]		0.045		0.611	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	58	109	4	9	
Mean (StdDev)	2.82 (2.650)	2.33 (2.448)	3.41 (1.860)	3.93 (3.565)	
Median	1.79	1.75	3.50	4.00	
Min, Max	0.0, 8.6	0.0, 9.8	1.2, 5.4	0.0, 10.0	
C6D1 CFB					
n	58	109	4	9	
LS Mean (StdErr) [2]	-0.80 (0.289)	-1.38 (0.222)	1.74 (1.496)	0.62 (1.186)	
95% CI [2]	-1.37, -0.23	-1.82, -0.94	-1.65, 5.12	-2.07, 3.30	
Difference (95% CI) in CFB [2]		-0.59 (-1.22, 0.05)		-1.12 (-4.04, 1.80)	
p-value [3]		0.071		0.407	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	59	106	3	9	
Mean (StdDev)	2.82 (2.710)	2.34 (2.481)	3.81 (1.075)	3.95 (3.389)	
Median	1.93	1.62	4.36	4.00	
Min, Max	0.0, 10.0	0.0, 9.8	2.6, 4.5	0.0, 10.0	
C7D1 CFB					
n	59	106	3	9	
LS Mean (StdErr) [2]	-0.84 (0.297)	-1.35 (0.233)	2.19 (1.909)	0.53 (1.389)	
95% CI [2]	-1.43, -0.26	-1.81, -0.89	-2.21, 6.59	-2.67, 3.74	
Difference (95% CI) in CFB [2]		-0.51 (-1.16, 0.15)		-1.65 (-5.35, 2.04)	
Hedges'G (95% CI) in CFB		-0.21 (-0.54, 0.10)		-0.38 (-1.98, 1.02)	
p-value [3]		0.130		0.332	
					0.639

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	63	114	4	9	
Mean (StdDev)	5.20 (2.656)	5.70 (2.414)	5.70 (3.390)	5.31 (2.810)	
Median	5.36	5.95	6.50	5.64	
Min, Max	0.0, 10.0	0.0, 10.0	1.3, 8.5	0.0, 9.9	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	63	110	4	9	
Mean (StdDev)	4.66 (2.668)	4.96 (2.675)	5.11 (2.360)	4.97 (3.014)	
Median	4.36	4.93	5.43	5.07	
Min, Max	0.0, 10.0	0.0, 10.0	2.4, 7.2	0.0, 10.0	
C2D1 CFB					
n	63	110	4	9	
LS Mean (StdErr) [2]	-0.50 (0.157)	-0.72 (0.127)	-0.18 (1.007)	-0.02 (0.798)	
95% CI [2]	-0.81, -0.19	-0.97, -0.47	-2.46, 2.09	-1.82, 1.79	
Difference (95% CI) in CFB [2]		-0.22 (-0.57, 0.12)		0.16 (-1.80, 2.13)	
p-value [3]		0.205		0.854	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	63	108	4	9	
Mean (StdDev)	4.48 (2.728)	4.60 (2.727)	4.68 (2.032)	4.88 (3.325)	
Median	4.15	4.45	4.50	4.62	
Min, Max	0.0, 10.0	0.0, 10.0	2.8, 6.9	0.0, 10.0	
C3D1 CFB					
n	63	108	4	9	
LS Mean (StdErr) [2]	-0.65 (0.190)	-1.08 (0.154)	-0.30 (1.443)	-0.04 (1.143)	
95% CI [2]	-1.03, -0.28	-1.39, -0.78	-3.56, 2.97	-2.63, 2.54	
Difference (95% CI) in CFB [2]		-0.43 (-0.85, -0.01)		0.25 (-2.56, 3.07)	
p-value [3]		0.046		0.842	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	60	108	4	9	
Mean (StdDev)	4.29 (2.813)	4.38 (2.816)	4.43 (1.754)	4.74 (3.539)	
Median	4.21	4.24	3.89	4.15	
Min, Max	0.0, 10.0	0.0, 10.0	3.1, 6.9	0.0, 9.9	
C4D1 CFB					
n	60	108	4	9	
LS Mean (StdErr) [2]	-0.84 (0.239)	-1.26 (0.189)	-0.47 (1.834)	-0.08 (1.453)	
95% CI [2]	-1.32, -0.37	-1.64, -0.89	-4.62, 3.68	-3.37, 3.21	
Difference (95% CI) in CFB [2]		-0.42 (-0.94, 0.11)		0.39 (-3.18, 3.97)	
p-value [3]		0.118		0.809	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	59	110	4	9	
Mean (StdDev)	4.05 (2.820)	4.31 (2.788)	4.62 (2.188)	5.04 (3.989)	
Median	3.79	4.55	4.21	5.64	
Min, Max	0.0, 10.0	0.0, 10.0	2.5, 7.5	0.0, 10.0	
C5D1 CFB					
n	59	110	4	9	
LS Mean (StdErr) [2]	-0.98 (0.255)	-1.23 (0.197)	0.22 (2.228)	0.49 (1.766)	
95% CI [2]	-1.49, -0.48	-1.62, -0.84	-4.82, 5.26	-3.50, 4.48	
Difference (95% CI) in CFB [2]		-0.25 (-0.81, 0.31)		0.27 (-4.08, 4.62)	
p-value [3]		0.382		0.891	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	58	109	4	9	
Mean (StdDev)	4.12 (2.776)	4.17 (2.883)	4.86 (1.669)	4.32 (3.762)	
Median	3.89	4.07	4.64	4.50	
Min, Max	0.0, 10.0	0.0, 10.0	3.4, 6.8	0.0, 10.0	
C6D1 CFB					
n	58	109	4	9	
LS Mean (StdErr) [2]	-0.83 (0.259)	-1.35 (0.200)	0.55 (1.740)	0.01 (1.379)	
95% CI [2]	-1.35, -0.32	-1.75, -0.96	-3.38, 4.49	-3.11, 3.13	
Difference (95% CI) in CFB [2]		-0.52 (-1.09, 0.05)		-0.55 (-3.94, 2.85)	
p-value [3]		0.075		0.724	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	59	106	3	9	
Mean (StdDev)	4.15 (2.874)	4.11 (2.921)	5.02 (1.858)	4.16 (3.726)	
Median	3.79	4.39	5.07	3.43	
Min, Max	0.0, 10.0	0.0, 10.0	3.1, 6.9	0.0, 10.0	
C7D1 CFB					
n	59	106	3	9	
LS Mean (StdErr) [2]	-0.86 (0.271)	-1.42 (0.212)	0.40 (1.970)	-0.06 (1.433)	
95% CI [2]	-1.39, -0.32	-1.84, -1.00	-4.14, 4.94	-3.36, 3.25	
Difference (95% CI) in CFB [2]		-0.56 (-1.16, 0.04)		-0.46 (-4.27, 3.36)	
Hedges'G (95% CI) in CFB		-0.26 (-0.58, 0.06)		-0.10 (-1.61, 1.36)	
p-value [3]		0.068		0.789	
					0.719

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	63	114	4	9	
Mean (StdDev)	4.24 (2.786)	4.25 (2.405)	4.45 (0.741)	5.27 (3.260)	
Median	4.64	4.00	4.25	5.43	
Min, Max	0.0, 9.9	0.0, 9.7	3.8, 5.5	0.8, 9.9	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	63	110	4	9	
Mean (StdDev)	3.91 (2.651)	3.66 (2.328)	4.04 (1.450)	4.52 (3.404)	
Median	4.00	3.55	3.82	3.36	
Min, Max	0.0, 9.1	0.0, 8.6	2.5, 6.0	0.1, 10.0	
C2D1 CFB					
n	63	110	4	9	
LS Mean (StdErr) [2]	-0.34 (0.177)	-0.60 (0.143)	0.08 (0.985)	-0.50 (0.780)	
95% CI [2]	-0.68, 0.01	-0.88, -0.32	-2.15, 2.31	-2.27, 1.26	
Difference (95% CI) in CFB [2]		-0.27 (-0.66, 0.13)		-0.59 (-2.51, 1.34)	
p-value [3]		0.182		0.508	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	63	108	4	9	
Mean (StdDev)	3.53 (2.626)	3.28 (2.264)	3.96 (1.387)	4.26 (3.653)	
Median	3.08	2.71	3.93	3.57	
Min, Max	0.0, 9.1	0.0, 8.3	2.4, 5.6	0.2, 10.0	
C3D1 CFB					
n	63	108	4	9	
LS Mean (StdErr) [2]	-0.64 (0.229)	-0.89 (0.185)	0.20 (1.274)	-0.52 (1.010)	
95% CI [2]	-1.09, -0.19	-1.26, -0.53	-2.68, 3.09	-2.80, 1.77	
Difference (95% CI) in CFB [2]		-0.25 (-0.76, 0.26)		-0.72 (-3.21, 1.77)	
p-value [3]		0.332		0.529	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	60	108	4	9	
Mean (StdDev)	3.58 (2.529)	3.12 (2.209)	4.27 (1.284)	4.35 (3.695)	
Median	3.22	2.83	4.29	3.08	
Min, Max	0.0, 8.4	0.0, 7.7	2.8, 5.7	0.0, 9.9	
C4D1 CFB					
n	60	108	4	9	
LS Mean (StdErr) [2]	-0.68 (0.260)	-1.09 (0.206)	0.78 (1.088)	-0.20 (0.862)	
95% CI [2]	-1.19, -0.16	-1.50, -0.69	-1.68, 3.24	-2.15, 1.75	
Difference (95% CI) in CFB [2]		-0.42 (-0.99, 0.15)		-0.99 (-3.11, 1.14)	
p-value [3]		0.151		0.321	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	59	110	4	9	
Mean (StdDev)	3.57 (2.521)	2.98 (2.106)	3.41 (1.945)	4.55 (4.254)	
Median	2.92	2.68	3.83	4.57	
Min, Max	0.0, 9.1	0.0, 8.4	0.7, 5.3	0.0, 10.0	
C5D1 CFB					
n	59	110	4	9	
LS Mean (StdErr) [2]	-0.75 (0.249)	-1.26 (0.192)	0.32 (1.527)	-0.16 (1.210)	
95% CI [2]	-1.24, -0.26	-1.64, -0.88	-3.13, 3.78	-2.90, 2.58	
Difference (95% CI) in CFB [2]		-0.51 (-1.06, 0.03)		-0.49 (-3.47, 2.49)	
p-value [3]		0.065		0.720	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	58	109	4	9	
Mean (StdDev)	3.25 (2.543)	2.73 (2.221)	3.82 (1.095)	4.10 (4.184)	
Median	2.74	2.14	3.57	1.50	
Min, Max	0.0, 8.9	0.0, 10.0	2.8, 5.4	0.1, 10.0	
C6D1 CFB					
n	58	109	4	9	
LS Mean (StdErr) [2]	-0.96 (0.266)	-1.50 (0.205)	0.79 (1.116)	-0.35 (0.884)	
95% CI [2]	-1.49, -0.44	-1.90, -1.09	-1.73, 3.32	-2.35, 1.65	
Difference (95% CI) in CFB [2]		-0.53 (-1.12, 0.05)		-1.14 (-3.32, 1.03)	
p-value [3]		0.075		0.265	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	59	106	3	9	
Mean (StdDev)	3.29 (2.665)	2.68 (2.184)	4.17 (1.053)	4.25 (4.013)	
Median	2.50	2.32	3.79	3.07	
Min, Max	0.0, 8.9	0.0, 9.6	3.4, 5.4	0.0, 10.0	
C7D1 CFB					
n	59	106	3	9	
LS Mean (StdErr) [2]	-0.92 (0.259)	-1.50 (0.203)	0.41 (1.508)	-0.46 (1.097)	
95% CI [2]	-1.43, -0.41	-1.90, -1.10	-3.07, 3.88	-2.99, 2.07	
Difference (95% CI) in CFB [2]		-0.58 (-1.15, -0.01)		-0.87 (-3.79, 2.06)	
Hedges'G (95% CI) in CFB		-0.28 (-0.61, 0.04)		-0.25 (-1.81, 1.17)	
p-value [3]		0.048		0.514	
					0.881

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	63	114	4	9	
Mean (StdDev)	1.57 (1.531)	1.52 (1.697)	1.09 (0.868)	1.67 (1.941)	
Median	1.15	1.00	1.25	0.93	
Min, Max	0.0, 7.2	0.0, 12.2	0.0, 1.9	0.0, 5.4	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	63	110	4	9	
Mean (StdDev)	1.29 (1.317)	1.16 (1.465)	0.95 (0.763)	1.23 (1.649)	
Median	0.71	0.77	0.75	0.86	
Min, Max	0.0, 4.9	0.0, 10.7	0.3, 2.0	0.0, 4.8	
C2D1 CFB					
n	63	110	4	9	
LS Mean (StdErr) [2]	-0.37 (0.120)	-0.45 (0.097)	0.12 (0.806)	-0.21 (0.638)	
95% CI [2]	-0.60, -0.13	-0.65, -0.26	-1.71, 1.94	-1.65, 1.24	
Difference (95% CI) in CFB [2]		-0.09 (-0.36, 0.18)		-0.32 (-1.90, 1.25)	
p-value [3]		0.516		0.651	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	63	108	4	9	
Mean (StdDev)	1.17 (1.206)	1.05 (1.222)	1.29 (0.456)	0.95 (1.266)	
Median	0.64	0.74	1.14	0.43	
Min, Max	0.0, 4.4	0.0, 5.8	0.9, 1.9	0.0, 3.8	
C3D1 CFB					
n	63	108	4	9	
LS Mean (StdErr) [2]	-0.50 (0.154)	-0.58 (0.125)	0.60 (1.274)	-0.38 (1.010)	
95% CI [2]	-0.81, -0.20	-0.82, -0.33	-2.28, 3.49	-2.66, 1.90	
Difference (95% CI) in CFB [2]		-0.08 (-0.42, 0.27)		-0.99 (-3.47, 1.50)	
p-value [3]		0.664		0.393	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	60	108	4	9	
Mean (StdDev)	1.16 (1.156)	1.04 (1.374)	1.48 (1.027)	1.08 (2.049)	
Median	0.76	0.57	1.14	0.14	
Min, Max	0.0, 4.8	0.0, 9.0	0.7, 2.9	0.0, 6.2	
C4D1 CFB					
n	60	108	4	9	
LS Mean (StdErr) [2]	-0.53 (0.146)	-0.55 (0.116)	0.79 (1.366)	-0.14 (1.083)	
95% CI [2]	-0.82, -0.24	-0.78, -0.32	-2.30, 3.88	-2.59, 2.31	
Difference (95% CI) in CFB [2]		-0.02 (-0.34, 0.30)		-0.93 (-3.59, 1.74)	
p-value [3]		0.895		0.451	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	59	110	4	9	
Mean (StdDev)	1.18 (1.220)	0.98 (1.328)	0.79 (0.810)	1.69 (2.925)	
Median	0.71	0.52	0.64	0.00	
Min, Max	0.0, 4.8	0.0, 9.6	0.0, 1.9	0.0, 8.1	
C5D1 CFB					
n	59	110	4	9	
LS Mean (StdErr) [2]	-0.52 (0.158)	-0.65 (0.122)	-0.29 (1.924)	0.11 (1.525)	
95% CI [2]	-0.83, -0.21	-0.89, -0.41	-4.64, 4.07	-3.34, 3.56	
Difference (95% CI) in CFB [2]		-0.13 (-0.48, 0.21)		0.39 (-3.36, 4.15)	
p-value [3]		0.451		0.818	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	58	109	4	9	
Mean (StdDev)	1.09 (1.309)	0.98 (1.286)	1.04 (1.227)	0.95 (1.759)	
Median	0.64	0.50	0.68	0.00	
Min, Max	0.0, 6.5	0.0, 9.0	0.0, 2.8	0.0, 5.2	
C6D1 CFB					
n	58	109	4	9	
LS Mean (StdErr) [2]	-0.54 (0.144)	-0.62 (0.111)	0.46 (1.250)	-0.07 (0.990)	
95% CI [2]	-0.82, -0.25	-0.83, -0.40	-2.36, 3.29	-2.31, 2.17	
Difference (95% CI) in CFB [2]		-0.08 (-0.40, 0.24)		-0.54 (-2.97, 1.90)	
p-value [3]		0.621		0.631	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	59	106	3	9	
Mean (StdDev)	1.11 (1.282)	0.87 (1.071)	0.38 (0.393)	0.88 (1.583)	
Median	0.54	0.35	0.36	0.14	
Min, Max	0.0, 5.9	0.0, 4.3	0.0, 0.8	0.0, 4.8	
C7D1 CFB					
n	59	106	3	9	
LS Mean (StdErr) [2]	-0.49 (0.159)	-0.63 (0.124)	0.13 (1.355)	-0.26 (0.986)	
95% CI [2]	-0.81, -0.18	-0.87, -0.38	-2.99, 3.25	-2.53, 2.02	
Difference (95% CI) in CFB [2]		-0.14 (-0.49, 0.21)		-0.39 (-3.01, 2.24)	
Hedges'G (95% CI) in CFB		-0.11 (-0.43, 0.21)		-0.13 (-1.64, 1.33)	
p-value [3]		0.442		0.743	
					0.869

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	63	114	4	9	
Mean (StdDev)	3.20 (2.604)	3.05 (2.389)	2.89 (3.455)	3.18 (2.973)	
Median	2.77	2.56	1.86	2.14	
Min, Max	0.0, 9.5	0.0, 9.5	0.0, 7.9	0.0, 7.7	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	63	110	4	9	
Mean (StdDev)	2.52 (2.469)	2.35 (2.335)	1.68 (1.115)	2.82 (2.811)	
Median	1.85	1.50	1.71	2.21	
Min, Max	0.0, 9.1	0.0, 8.9	0.6, 2.6	0.0, 7.4	
C2D1 CFB					
n	63	110	4	9	
LS Mean (StdErr) [2]	-0.61 (0.197)	-0.65 (0.159)	-0.83 (1.342)	0.35 (1.063)	
95% CI [2]	-1.00, -0.22	-0.97, -0.34	-3.87, 2.21	-2.06, 2.75	
Difference (95% CI) in CFB [2]		-0.04 (-0.48, 0.39)		1.18 (-1.44, 3.80)	
p-value [3]		0.849		0.336	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	63	108	4	9	
Mean (StdDev)	2.33 (2.358)	2.15 (2.195)	2.43 (1.008)	2.41 (2.805)	
Median	1.43	1.54	2.18	0.93	
Min, Max	0.0, 8.7	0.0, 9.5	1.5, 3.9	0.0, 7.7	
C3D1 CFB					
n	63	108	4	9	
LS Mean (StdErr) [2]	-0.76 (0.242)	-0.80 (0.196)	0.08 (1.789)	-0.10 (1.418)	
95% CI [2]	-1.24, -0.28	-1.18, -0.41	-3.97, 4.13	-3.31, 3.11	
Difference (95% CI) in CFB [2]		-0.04 (-0.57, 0.50)		-0.18 (-3.67, 3.31)	
p-value [3]		0.895		0.911	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	60	108	4	9	
Mean (StdDev)	2.53 (2.415)	2.10 (2.268)	2.61 (1.515)	1.98 (2.977)	
Median	1.84	1.32	2.39	0.50	
Min, Max	0.0, 8.3	0.0, 8.3	1.0, 4.6	0.0, 8.9	
C4D1 CFB					
n	60	108	4	9	
LS Mean (StdErr) [2]	-0.67 (0.235)	-0.87 (0.186)	0.62 (1.994)	0.01 (1.580)	
95% CI [2]	-1.13, -0.20	-1.24, -0.51	-3.89, 5.13	-3.56, 3.59	
Difference (95% CI) in CFB [2]		-0.21 (-0.73, 0.31)		-0.61 (-4.50, 3.28)	
p-value [3]		0.424		0.732	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	59	110	4	9	
Mean (StdDev)	2.54 (2.426)	1.96 (2.087)	1.32 (1.254)	2.60 (3.868)	
Median	1.36	1.25	1.43	0.00	
Min, Max	0.0, 8.5	0.0, 8.0	0.0, 2.4	0.0, 9.0	
C5D1 CFB					
n	59	110	4	9	
LS Mean (StdErr) [2]	-0.71 (0.267)	-1.07 (0.206)	-1.04 (2.068)	0.30 (1.639)	
95% CI [2]	-1.24, -0.19	-1.48, -0.66	-5.72, 3.64	-3.40, 4.01	
Difference (95% CI) in CFB [2]		-0.36 (-0.94, 0.23)		1.34 (-2.69, 5.38)	
p-value [3]		0.231		0.470	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	58	109	4	9	
Mean (StdDev)	2.33 (2.418)	1.94 (2.191)	1.70 (1.634)	1.76 (2.822)	
Median	1.55	1.21	1.43	0.00	
Min, Max	0.0, 8.6	0.0, 8.9	0.0, 3.9	0.0, 8.1	
C6D1 CFB					
n	58	109	4	9	
LS Mean (StdErr) [2]	-0.72 (0.253)	-1.02 (0.195)	-0.08 (1.872)	0.16 (1.483)	
95% CI [2]	-1.22, -0.22	-1.41, -0.64	-4.31, 4.15	-3.19, 3.52	
Difference (95% CI) in CFB [2]		-0.30 (-0.86, 0.26)		0.24 (-3.41, 3.90)	
p-value [3]		0.287		0.884	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	59	106	3	9	
Mean (StdDev)	2.33 (2.510)	1.87 (2.217)	0.95 (1.242)	1.81 (2.870)	
Median	1.36	0.81	0.50	0.29	
Min, Max	0.0, 8.6	0.0, 8.7	0.0, 2.4	0.0, 8.4	
C7D1 CFB					
n	59	106	3	9	
LS Mean (StdErr) [2]	-0.73 (0.278)	-1.07 (0.218)	-0.90 (1.958)	-0.22 (1.425)	
95% CI [2]	-1.28, -0.18	-1.50, -0.64	-5.42, 3.61	-3.51, 3.06	
Difference (95% CI) in CFB [2]		-0.34 (-0.95, 0.28)		0.68 (-3.11, 4.48)	
Hedges'G (95% CI) in CFB		-0.15 (-0.48, 0.17)		0.15 (-1.30, 1.68)	
p-value [3]		0.278		0.689	
					0.391

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	64	113	
Mean (StdDev)	2.79 (3.224)	7.32 (1.633)	5.67 (2.327)	5.46 (2.405)	
Median	1.14	7.75	5.79	5.90	
Min, Max	0.7, 6.5	4.0, 10.0	0.0, 10.0	0.0, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	64	109	
Mean (StdDev)	2.69 (3.306)	6.67 (1.844)	5.04 (2.524)	4.69 (2.571)	
Median	1.00	7.14	5.25	4.29	
Min, Max	0.6, 6.5	3.8, 9.3	0.0, 10.0	0.0, 10.0	
C2D1 CFB					
n	3	10	64	109	
LS Mean (StdErr) [2]	-0.05 (0.560)	-0.55 (0.495)	-0.58 (0.181)	-0.73 (0.147)	
95% CI [2]	-1.32, 1.22	-1.67, 0.57	-0.94, -0.22	-1.02, -0.44	
Difference (95% CI) in CFB [2]		-0.50 (-1.95, 0.95)		-0.15 (-0.55, 0.25)	
p-value [3]		0.456		0.453	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	8	64	109	
Mean (StdDev)	2.45 (3.362)	6.60 (2.152)	4.95 (2.591)	4.38 (2.659)	
Median	1.08	6.68	5.39	4.00	
Min, Max	0.0, 6.3	3.9, 10.0	0.0, 10.0	0.0, 10.0	
C3D1 CFB					
n	3	8	64	109	
LS Mean (StdErr) [2]	-0.27 (0.833)	-0.71 (0.735)	-0.70 (0.212)	-1.07 (0.172)	
95% CI [2]	-2.24, 1.70	-2.45, 1.03	-1.12, -0.28	-1.41, -0.73	
Difference (95% CI) in CFB [2]		-0.43 (-2.70, 1.83)		-0.36 (-0.83, 0.10)	
p-value [3]		0.664		0.125	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	3	9	61	108	
Mean (StdDev)	2.49 (3.409)	5.92 (2.333)	4.97 (2.681)	4.40 (2.804)	
Median	1.00	4.86	4.79	3.93	
Min, Max	0.1, 6.4	3.4, 9.8	0.0, 9.8	0.0, 10.0	
C4D1 CFB					
n	3	9	61	108	
LS Mean (StdErr) [2]	-0.26 (0.967)	-1.23 (0.855)	-0.64 (0.259)	-0.95 (0.205)	
95% CI [2]	-2.49, 1.97	-3.20, 0.74	-1.15, -0.13	-1.35, -0.54	
Difference (95% CI) in CFB [2]		-0.97 (-3.53, 1.58)		-0.30 (-0.87, 0.26)	
p-value [3]		0.406		0.290	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	9	60	110	
Mean (StdDev)	2.45 (3.158)	5.27 (2.301)	4.97 (2.681)	4.17 (2.838)	
Median	1.00	4.50	4.93	4.29	
Min, Max	0.3, 6.1	2.5, 8.6	0.0, 9.8	0.0, 10.0	
C5D1 CFB					
n	3	9	60	110	
LS Mean (StdErr) [2]	-0.44 (1.040)	-2.11 (0.919)	-0.56 (0.272)	-1.07 (0.211)	
95% CI [2]	-2.83, 1.96	-4.23, 0.01	-1.10, -0.03	-1.48, -0.65	
Difference (95% CI) in CFB [2]		-1.68 (-4.42, 1.07)		-0.50 (-1.09, 0.09)	
p-value [3]		0.197		0.098	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	59	109	
Mean (StdDev)	2.45 (3.158)	5.44 (2.009)	4.93 (2.660)	3.99 (2.772)	
Median	1.00	6.00	5.07	3.71	
Min, Max	0.3, 6.1	2.1, 7.6	0.0, 9.6	0.0, 10.0	
C6D1 CFB					
n	3	9	59	109	
LS Mean (StdErr) [2]	-0.52 (1.021)	-2.13 (0.903)	-0.45 (0.278)	-1.19 (0.215)	
95% CI [2]	-2.87, 1.84	-4.21, -0.04	-1.00, 0.10	-1.61, -0.77	
Difference (95% CI) in CFB [2]		-1.61 (-4.30, 1.09)		-0.74 (-1.35, -0.13)	
p-value [3]		0.207		0.018	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bone Pain Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	9	59	106	
Mean (StdDev)	2.33 (3.008)	5.09 (2.102)	4.87 (2.668)	3.93 (2.851)	
Median	0.92	3.64	5.33	3.49	
Min, Max	0.3, 5.8	2.8, 8.2	0.0, 9.4	0.0, 10.0	
C7D1 CFB					
n	3	9	59	106	
LS Mean (StdErr) [2]	-0.72 (0.876)	-2.60 (0.774)	-0.56 (0.290)	-1.20 (0.226)	
95% CI [2]	-2.74, 1.30	-4.38, -0.82	-1.13, 0.01	-1.65, -0.75	
Difference (95% CI) in CFB [2]		-1.88 (-4.19, 0.43)		-0.64 (-1.27, -0.00)	
Hedges'G (95% CI) in CFB		-0.79 (-2.54, 0.55)		-0.28 (-0.60, 0.04)	
p-value [3]		0.098		0.049	
					0.484

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	64	113	
Mean (StdDev)	3.10 (3.032)	5.80 (1.830)	4.23 (2.399)	4.02 (2.163)	
Median	1.71	5.93	4.23	3.92	
Min, Max	1.0, 6.6	2.9, 8.5	0.0, 9.6	0.0, 9.8	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	64	109	
Mean (StdDev)	3.07 (2.764)	4.79 (2.032)	3.39 (2.182)	3.24 (2.131)	
Median	2.29	5.29	3.46	3.00	
Min, Max	0.8, 6.1	0.4, 7.3	0.0, 8.9	0.0, 9.4	
C2D1 CFB					
n	3	10	64	109	
LS Mean (StdErr) [2]	0.30 (0.572)	-0.36 (0.506)	-0.79 (0.164)	-0.74 (0.133)	
95% CI [2]	-1.00, 1.59	-1.51, 0.78	-1.12, -0.47	-1.01, -0.48	
Difference (95% CI) in CFB [2]		-0.66 (-2.14, 0.82)		0.05 (-0.31, 0.41)	
p-value [3]		0.339		0.785	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	8	64	109	
Mean (StdDev)	2.45 (2.703)	3.97 (2.036)	3.21 (2.223)	2.86 (2.179)	
Median	0.92	4.32	3.00	2.46	
Min, Max	0.9, 5.6	0.3, 6.7	0.0, 8.4	0.0, 8.3	
C3D1 CFB					
n	3	8	64	109	
LS Mean (StdErr) [2]	-0.48 (0.432)	-1.45 (0.382)	-0.90 (0.210)	-1.04 (0.171)	
95% CI [2]	-1.50, 0.55	-2.35, -0.54	-1.32, -0.49	-1.38, -0.71	
Difference (95% CI) in CFB [2]		-0.97 (-2.15, 0.20)		-0.14 (-0.60, 0.32)	
p-value [3]		0.092		0.552	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	3	9	61	108	
Mean (StdDev)	2.21 (2.813)	3.41 (1.756)	3.20 (2.161)	2.61 (2.227)	
Median	0.64	3.14	3.29	2.07	
Min, Max	0.5, 5.5	0.1, 6.5	0.0, 7.9	0.0, 9.1	
C4D1 CFB					
n	3	9	61	108	
LS Mean (StdErr) [2]	-0.91 (0.677)	-2.53 (0.598)	-0.98 (0.252)	-1.28 (0.200)	
95% CI [2]	-2.47, 0.65	-3.91, -1.15	-1.47, -0.48	-1.67, -0.88	
Difference (95% CI) in CFB [2]		-1.62 (-3.41, 0.17)		-0.30 (-0.85, 0.25)	
p-value [3]		0.070		0.285	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	9	60	110	
Mean (StdDev)	2.25 (2.607)	2.79 (1.728)	3.29 (2.188)	2.56 (2.333)	
Median	1.14	2.91	3.04	1.93	
Min, Max	0.4, 5.2	0.0, 6.5	0.0, 8.1	0.0, 9.4	
C5D1 CFB					
n	3	9	60	110	
LS Mean (StdErr) [2]	-0.84 (0.881)	-3.09 (0.779)	-0.88 (0.276)	-1.30 (0.214)	
95% CI [2]	-2.88, 1.19	-4.89, -1.30	-1.43, -0.34	-1.72, -0.88	
Difference (95% CI) in CFB [2]		-2.25 (-4.58, 0.08)		-0.42 (-1.02, 0.18)	
p-value [3]		0.056		0.172	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	59	109	
Mean (StdDev)	2.15 (2.639)	2.59 (1.967)	2.73 (2.087)	2.42 (2.301)	
Median	1.07	2.79	2.54	1.92	
Min, Max	0.2, 5.2	0.0, 6.6	0.0, 7.1	0.0, 9.6	
C6D1 CFB					
n	3	9	59	109	
LS Mean (StdErr) [2]	-1.13 (1.112)	-3.64 (0.983)	-1.24 (0.277)	-1.38 (0.214)	
95% CI [2]	-3.70, 1.43	-5.91, -1.37	-1.78, -0.69	-1.80, -0.96	
Difference (95% CI) in CFB [2]		-2.50 (-5.44, 0.43)		-0.14 (-0.75, 0.46)	
p-value [3]		0.085		0.640	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Abdominal Pain Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	9	59	106	
Mean (StdDev)	2.46 (2.415)	3.13 (2.349)	2.91 (2.324)	2.40 (2.218)	
Median	2.00	3.00	2.71	1.96	
Min, Max	0.3, 5.1	0.0, 7.2	0.0, 8.3	0.0, 9.4	
C7D1 CFB					
n	3	9	59	106	
LS Mean (StdErr) [2]	-0.93 (1.315)	-3.34 (1.163)	-1.13 (0.271)	-1.39 (0.212)	
95% CI [2]	-3.97, 2.10	-6.02, -0.66	-1.67, -0.60	-1.81, -0.97	
Difference (95% CI) in CFB [2]		-2.40 (-5.88, 1.07)		-0.26 (-0.85, 0.33)	
Hedges'G (95% CI) in CFB		-0.68 (-2.37, 0.68)		-0.12 (-0.44, 0.20)	
p-value [3]		0.149		0.391	
					0.168

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	64	113	
Mean (StdDev)	2.60 (2.640)	3.65 (2.634)	3.58 (2.472)	3.17 (2.519)	
Median	1.14	2.77	3.29	2.83	
Min, Max	1.0, 5.6	0.0, 8.4	0.0, 8.9	0.0, 9.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	64	109	
Mean (StdDev)	2.57 (2.557)	3.42 (2.316)	3.01 (2.370)	2.67 (2.363)	
Median	1.43	3.61	2.56	2.25	
Min, Max	0.8, 5.5	0.0, 6.9	0.0, 8.3	0.0, 8.8	
C2D1 CFB					
n	3	10	64	109	
LS Mean (StdErr) [2]	0.12 (0.709)	0.05 (0.627)	-0.50 (0.178)	-0.43 (0.144)	
95% CI [2]	-1.48, 1.72	-1.37, 1.47	-0.85, -0.15	-0.72, -0.15	
Difference (95% CI) in CFB [2]		-0.07 (-1.90, 1.76)		0.07 (-0.32, 0.46)	
p-value [3]		0.933		0.725	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	8	64	109	
Mean (StdDev)	2.24 (2.795)	2.67 (2.122)	2.67 (2.302)	2.41 (2.303)	
Median	1.08	2.57	2.19	1.79	
Min, Max	0.2, 5.4	0.0, 6.0	0.0, 7.7	0.0, 8.9	
C3D1 CFB					
n	3	8	64	109	
LS Mean (StdErr) [2]	-0.28 (0.848)	-0.60 (0.749)	-0.86 (0.214)	-0.70 (0.174)	
95% CI [2]	-2.28, 1.73	-2.38, 1.17	-1.28, -0.43	-1.04, -0.35	
Difference (95% CI) in CFB [2]		-0.33 (-2.63, 1.98)		0.16 (-0.31, 0.63)	
p-value [3]		0.747		0.504	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	3	9	61	108	
Mean (StdDev)	2.12 (2.965)	2.46 (1.895)	2.77 (2.215)	2.13 (2.280)	
Median	0.62	2.14	2.07	1.41	
Min, Max	0.2, 5.5	0.0, 6.6	0.0, 7.4	0.0, 9.2	
C4D1 CFB					
n	3	9	61	108	
LS Mean (StdErr) [2]	-0.72 (0.963)	-1.69 (0.852)	-0.86 (0.247)	-0.98 (0.196)	
95% CI [2]	-2.95, 1.50	-3.65, 0.28	-1.34, -0.37	-1.36, -0.59	
Difference (95% CI) in CFB [2]		-0.96 (-3.51, 1.58)		-0.12 (-0.66, 0.42)	
p-value [3]		0.408		0.660	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	9	60	110	
Mean (StdDev)	2.09 (2.658)	1.98 (1.757)	2.83 (2.206)	2.14 (2.291)	
Median	0.77	1.77	2.77	1.44	
Min, Max	0.4, 5.2	0.0, 5.7	0.0, 8.5	0.0, 8.9	
C5D1 CFB					
n	3	9	60	110	
LS Mean (StdErr) [2]	-0.76 (0.994)	-2.15 (0.879)	-0.80 (0.270)	-0.92 (0.209)	
95% CI [2]	-3.05, 1.54	-4.18, -0.13	-1.33, -0.26	-1.33, -0.51	
Difference (95% CI) in CFB [2]		-1.40 (-4.02, 1.23)		-0.13 (-0.71, 0.46)	
p-value [3]		0.255		0.674	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	59	109	
Mean (StdDev)	1.84 (2.874)	1.74 (1.668)	2.49 (2.088)	1.91 (2.226)	
Median	0.29	1.36	2.21	1.38	
Min, Max	0.1, 5.2	0.0, 5.4	0.0, 7.9	0.0, 9.9	
C6D1 CFB					
n	3	9	59	109	
LS Mean (StdErr) [2]	-1.29 (1.313)	-2.95 (1.161)	-1.09 (0.263)	-1.12 (0.203)	
95% CI [2]	-4.32, 1.74	-5.63, -0.28	-1.61, -0.57	-1.53, -0.72	
Difference (95% CI) in CFB [2]		-1.66 (-5.13, 1.81)		-0.03 (-0.61, 0.54)	
p-value [3]		0.302		0.908	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Nausea Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	9	59	106	
Mean (StdDev)	2.29 (2.514)	2.14 (2.060)	2.57 (2.278)	1.93 (2.201)	
Median	1.36	2.00	2.25	1.26	
Min, Max	0.4, 5.1	0.0, 6.3	0.0, 7.7	0.0, 9.5	
C7D1 CFB					
n	3	9	59	106	
LS Mean (StdErr) [2]	-0.72 (1.416)	-2.35 (1.252)	-0.99 (0.286)	-1.08 (0.223)	
95% CI [2]	-3.99, 2.54	-5.23, 0.54	-1.55, -0.42	-1.52, -0.64	
Difference (95% CI) in CFB [2]		-1.63 (-5.37, 2.12)		-0.09 (-0.72, 0.54)	
Hedges'G (95% CI) in CFB		-0.42 (-2.03, 0.97)		-0.04 (-0.36, 0.28)	
p-value [3]		0.346		0.775	
					0.462

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	64	113	
Mean (StdDev)	8.07 (0.895)	6.08 (3.642)	5.94 (3.050)	5.50 (2.969)	
Median	8.00	5.96	6.48	6.00	
Min, Max	7.2, 9.0	0.0, 10.0	0.0, 10.0	0.0, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	64	109	
Mean (StdDev)	7.81 (1.014)	5.61 (3.032)	5.52 (2.880)	4.56 (2.731)	
Median	8.00	6.00	5.71	4.69	
Min, Max	6.7, 8.7	0.0, 9.5	0.0, 10.0	0.0, 10.0	
C2D1 CFB					
n	3	10	64	109	
LS Mean (StdErr) [2]	-0.18 (0.891)	-0.30 (0.788)	-0.35 (0.172)	-0.90 (0.140)	
95% CI [2]	-2.20, 1.83	-2.08, 1.48	-0.69, -0.01	-1.17, -0.62	
Difference (95% CI) in CFB [2]		-0.12 (-2.42, 2.19)		-0.55 (-0.93, -0.17)	
p-value [3]		0.911		0.005	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	8	64	109	
Mean (StdDev)	7.48 (0.907)	4.77 (3.116)	5.49 (2.947)	4.17 (2.575)	
Median	8.00	4.93	5.45	4.00	
Min, Max	6.4, 8.0	0.0, 8.9	0.0, 10.0	0.0, 9.8	
C3D1 CFB					
n	3	8	64	109	
LS Mean (StdErr) [2]	-0.09 (1.160)	-0.92 (1.025)	-0.31 (0.213)	-1.20 (0.173)	
95% CI [2]	-2.83, 2.66	-3.34, 1.50	-0.73, 0.11	-1.54, -0.86	
Difference (95% CI) in CFB [2]		-0.83 (-3.99, 2.32)		-0.89 (-1.36, -0.42)	
p-value [3]		0.552		<0.001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	3	9	61	108	
Mean (StdDev)	7.60 (0.701)	4.37 (2.749)	5.39 (2.955)	3.96 (2.594)	
Median	8.00	3.57	5.36	3.85	
Min, Max	6.8, 8.0	0.0, 8.2	0.0, 10.0	0.0, 9.4	
C4D1 CFB					
n	3	9	61	108	
LS Mean (StdErr) [2]	0.08 (1.223)	-0.81 (1.081)	-0.22 (0.227)	-1.32 (0.180)	
95% CI [2]	-2.74, 2.90	-3.31, 1.68	-0.67, 0.23	-1.68, -0.97	
Difference (95% CI) in CFB [2]		-0.90 (-4.13, 2.34)		-1.10 (-1.59, -0.60)	
p-value [3]		0.540		<0.0001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	9	60	110	
Mean (StdDev)	7.36 (1.113)	4.34 (2.886)	5.30 (2.944)	3.71 (2.552)	
Median	8.00	3.27	5.11	3.25	
Min, Max	6.1, 8.0	0.6, 8.6	0.0, 10.0	0.0, 9.9	
C5D1 CFB					
n	3	9	60	110	
LS Mean (StdErr) [2]	-0.29 (1.371)	-1.04 (1.212)	-0.33 (0.247)	-1.56 (0.191)	
95% CI [2]	-3.45, 2.87	-3.83, 1.76	-0.82, 0.15	-1.94, -1.18	
Difference (95% CI) in CFB [2]		-0.75 (-4.37, 2.87)		-1.23 (-1.76, -0.69)	
p-value [3]		0.647		<0.0001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	59	109	
Mean (StdDev)	6.93 (1.338)	4.34 (2.603)	5.40 (2.962)	3.53 (2.578)	
Median	7.36	4.46	5.00	3.17	
Min, Max	5.4, 8.0	0.3, 8.0	0.0, 10.0	0.0, 10.0	
C6D1 CFB					
n	3	9	59	109	
LS Mean (StdErr) [2]	-0.74 (1.553)	-1.10 (1.372)	-0.17 (0.287)	-1.63 (0.222)	
95% CI [2]	-4.32, 2.84	-4.26, 2.07	-0.73, 0.40	-2.07, -1.19	
Difference (95% CI) in CFB [2]		-0.36 (-4.46, 3.74)		-1.46 (-2.09, -0.83)	
p-value [3]		0.845		<0.0001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Spots Severity

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	9	59	106	
Mean (StdDev)	7.10 (1.064)	3.90 (2.898)	5.43 (2.892)	3.53 (2.657)	
Median	7.38	3.33	5.00	3.12	
Min, Max	5.9, 8.0	0.0, 8.1	0.0, 10.0	0.0, 10.0	
C7D1 CFB					
n	3	9	59	106	
LS Mean (StdErr) [2]	-0.56 (1.367)	-1.54 (1.208)	-0.30 (0.300)	-1.69 (0.234)	
95% CI [2]	-3.71, 2.60	-4.33, 1.25	-0.89, 0.30	-2.16, -1.23	
Difference (95% CI) in CFB [2]		-0.98 (-4.59, 2.63)		-1.40 (-2.05, -0.74)	
Hedges'G (95% CI) in CFB		-0.27 (-1.82, 1.16)		-0.59 (-0.92, -0.27)	
p-value [3]		0.548		<0.0001	
					0.864

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	64	113	
Mean (StdDev)	7.50 (1.357)	7.35 (2.389)	5.90 (2.672)	5.28 (2.645)	
Median	7.14	7.43	6.28	5.36	
Min, Max	6.4, 9.0	3.3, 10.0	0.0, 10.0	0.0, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	64	109	
Mean (StdDev)	7.26 (1.580)	6.19 (1.645)	5.19 (2.754)	4.20 (2.359)	
Median	7.07	6.89	5.59	4.21	
Min, Max	5.8, 8.9	3.3, 8.6	0.0, 10.0	0.0, 9.9	
C2D1 CFB					
n	3	10	64	109	
LS Mean (StdErr) [2]	-0.18 (1.013)	-0.98 (0.896)	-0.77 (0.225)	-1.16 (0.183)	
95% CI [2]	-2.47, 2.11	-3.01, 1.04	-1.21, -0.32	-1.52, -0.80	
Difference (95% CI) in CFB [2]		-0.80 (-3.42, 1.81)		-0.39 (-0.89, 0.11)	
p-value [3]		0.505		0.122	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	8	64	109	
Mean (StdDev)	6.31 (0.913)	5.10 (1.672)	4.94 (2.783)	3.57 (2.461)	
Median	5.85	4.75	4.79	3.31	
Min, Max	5.7, 7.4	3.0, 8.0	0.0, 10.0	0.0, 9.7	
C3D1 CFB					
n	3	8	64	109	
LS Mean (StdErr) [2]	-0.93 (1.747)	-2.15 (1.543)	-0.87 (0.268)	-1.63 (0.218)	
95% CI [2]	-5.06, 3.20	-5.79, 1.50	-1.40, -0.34	-2.06, -1.20	
Difference (95% CI) in CFB [2]		-1.22 (-5.97, 3.53)		-0.76 (-1.35, -0.17)	
p-value [3]		0.563		0.012	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	3	9	61	108	
Mean (StdDev)	6.44 (0.766)	4.05 (2.276)	4.83 (2.845)	3.39 (2.567)	
Median	6.15	3.79	5.14	3.11	
Min, Max	5.9, 7.3	0.0, 8.0	0.0, 10.0	0.0, 10.0	
C4D1 CFB					
n	3	9	61	108	
LS Mean (StdErr) [2]	-0.74 (2.211)	-2.71 (1.954)	-1.05 (0.315)	-1.86 (0.250)	
95% CI [2]	-5.84, 4.35	-7.22, 1.80	-1.67, -0.42	-2.35, -1.37	
Difference (95% CI) in CFB [2]		-1.97 (-7.81, 3.88)		-0.82 (-1.50, -0.13)	
p-value [3]		0.460		0.020	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	9	60	110	
Mean (StdDev)	6.20 (1.630)	3.82 (2.552)	4.96 (2.691)	3.13 (2.518)	
Median	6.77	3.57	4.78	2.93	
Min, Max	4.4, 7.5	0.0, 7.5	0.0, 10.0	0.0, 10.0	
C5D1 CFB					
n	3	9	60	110	
LS Mean (StdErr) [2]	-1.37 (2.339)	-3.60 (2.067)	-0.83 (0.325)	-1.97 (0.252)	
95% CI [2]	-6.76, 4.02	-8.37, 1.16	-1.47, -0.19	-2.46, -1.47	
Difference (95% CI) in CFB [2]		-2.23 (-8.41, 3.95)		-1.14 (-1.85, -0.43)	
p-value [3]		0.429		0.002	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	59	109	
Mean (StdDev)	5.87 (1.554)	3.25 (2.441)	4.89 (2.716)	3.10 (2.562)	
Median	5.79	2.93	5.00	2.75	
Min, Max	4.4, 7.5	0.0, 6.9	0.0, 10.0	0.0, 10.0	
C6D1 CFB					
n	3	9	59	109	
LS Mean (StdErr) [2]	-1.70 (2.190)	-4.19 (1.935)	-0.95 (0.332)	-2.09 (0.257)	
95% CI [2]	-6.75, 3.35	-8.66, 0.27	-1.61, -0.30	-2.60, -1.59	
Difference (95% CI) in CFB [2]		-2.49 (-8.27, 3.30)		-1.14 (-1.87, -0.41)	
p-value [3]		0.350		0.002	

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Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Itching Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	9	59	106	
Mean (StdDev)	6.40 (1.346)	3.26 (2.228)	4.98 (2.586)	3.03 (2.537)	
Median	6.69	3.55	5.07	2.70	
Min, Max	4.9, 7.6	0.0, 6.6	0.0, 10.0	0.0, 10.0	
C7D1 CFB					
n	3	9	59	106	
LS Mean (StdErr) [2]	-1.08 (2.090)	-3.98 (1.847)	-0.95 (0.354)	-2.15 (0.276)	
95% CI [2]	-5.90, 3.74	-8.24, 0.28	-1.65, -0.25	-2.69, -1.60	
Difference (95% CI) in CFB [2]		-2.91 (-8.43, 2.62)		-1.19 (-1.97, -0.42)	
Hedges'G (95% CI) in CFB		-0.51 (-2.15, 0.86)		-0.42 (-0.75, -0.11)	
p-value [3]		0.260		0.003	
					0.319

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	64	113	
Mean (StdDev)	6.38 (2.425)	6.10 (2.862)	5.92 (2.574)	5.33 (2.369)	
Median	5.93	6.46	5.78	5.43	
Min, Max	4.2, 9.0	0.0, 9.9	0.0, 10.0	0.0, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	64	109	
Mean (StdDev)	6.31 (2.330)	4.77 (2.532)	5.34 (2.654)	4.68 (2.466)	
Median	5.79	4.86	5.01	4.79	
Min, Max	4.3, 8.9	0.0, 8.2	0.0, 10.0	0.0, 10.0	
C2D1 CFB					
n	3	10	64	109	
LS Mean (StdErr) [2]	-0.07 (0.851)	-1.26 (0.752)	-0.57 (0.208)	-0.67 (0.168)	
95% CI [2]	-1.99, 1.86	-2.96, 0.44	-0.98, -0.16	-1.01, -0.34	
Difference (95% CI) in CFB [2]		-1.19 (-3.39, 1.01)		-0.10 (-0.56, 0.36)	
p-value [3]		0.250		0.667	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	8	64	109	
Mean (StdDev)	5.88 (1.256)	4.38 (2.534)	5.17 (2.848)	4.13 (2.514)	
Median	5.86	4.25	5.20	4.17	
Min, Max	4.6, 7.2	0.6, 8.0	0.0, 10.0	0.0, 10.0	
C3D1 CFB					
n	3	8	64	109	
LS Mean (StdErr) [2]	-0.29 (1.364)	-1.71 (1.204)	-0.67 (0.247)	-1.14 (0.201)	
95% CI [2]	-3.52, 2.93	-4.56, 1.14	-1.16, -0.18	-1.54, -0.75	
Difference (95% CI) in CFB [2]		-1.42 (-5.12, 2.29)		-0.47 (-1.02, 0.07)	
p-value [3]		0.396		0.088	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	3	9	61	108	
Mean (StdDev)	5.86 (2.179)	3.57 (2.528)	5.13 (2.889)	3.95 (2.535)	
Median	5.92	3.46	4.71	3.78	
Min, Max	3.6, 8.0	0.0, 8.0	0.0, 10.0	0.0, 10.0	
C4D1 CFB					
n	3	9	61	108	
LS Mean (StdErr) [2]	-0.45 (1.164)	-2.52 (1.029)	-0.78 (0.289)	-1.39 (0.229)	
95% CI [2]	-3.13, 2.23	-4.89, -0.15	-1.35, -0.21	-1.84, -0.94	
Difference (95% CI) in CFB [2]		-2.07 (-5.15, 1.00)		-0.60 (-1.23, 0.02)	
p-value [3]		0.159		0.060	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

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[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	9	60	110	
Mean (StdDev)	5.66 (2.395)	3.12 (2.506)	5.18 (2.879)	3.78 (2.549)	
Median	5.77	2.38	5.21	3.88	
Min, Max	3.2, 8.0	0.2, 7.2	0.0, 10.0	0.0, 9.8	
C5D1 CFB					
n	3	9	60	110	
LS Mean (StdErr) [2]	-0.82 (1.326)	-3.25 (1.172)	-0.75 (0.318)	-1.55 (0.246)	
95% CI [2]	-3.87, 2.24	-5.95, -0.55	-1.38, -0.13	-2.03, -1.06	
Difference (95% CI) in CFB [2]		-2.43 (-5.93, 1.07)		-0.79 (-1.48, -0.10)	
p-value [3]		0.148		0.025	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	59	109	
Mean (StdDev)	5.12 (2.288)	2.78 (2.305)	5.05 (2.925)	3.66 (2.600)	
Median	5.23	3.07	5.00	3.57	
Min, Max	2.8, 7.4	0.0, 6.6	0.0, 10.0	0.0, 10.0	
C6D1 CFB					
n	3	9	59	109	
LS Mean (StdErr) [2]	-1.41 (1.322)	-3.68 (1.169)	-0.91 (0.329)	-1.67 (0.254)	
95% CI [2]	-4.46, 1.64	-6.38, -0.99	-1.56, -0.27	-2.18, -1.17	
Difference (95% CI) in CFB [2]		-2.27 (-5.77, 1.22)		-0.76 (-1.48, -0.04)	
p-value [3]		0.172		0.039	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Flushing Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	9	59	106	
Mean (StdDev)	5.37 (1.916)	2.93 (2.602)	5.11 (2.878)	3.39 (2.553)	
Median	5.14	3.23	5.36	3.04	
Min, Max	3.6, 7.4	0.0, 7.0	0.0, 10.0	0.0, 10.0	
C7D1 CFB					
n	3	9	59	106	
LS Mean (StdErr) [2]	-1.21 (1.544)	-3.63 (1.365)	-0.86 (0.342)	-1.80 (0.267)	
95% CI [2]	-4.77, 2.35	-6.78, -0.48	-1.54, -0.18	-2.33, -1.27	
Difference (95% CI) in CFB [2]		-2.42 (-6.50, 1.66)		-0.94 (-1.69, -0.19)	
Hedges'G (95% CI) in CFB		-0.58 (-2.24, 0.79)		-0.35 (-0.67, -0.03)	
p-value [3]		0.208		0.014	
					0.404

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	64	113	
Mean (StdDev)	5.71 (2.162)	7.45 (1.903)	6.84 (1.998)	6.90 (1.996)	
Median	6.43	8.05	6.75	7.00	
Min, Max	3.3, 7.4	3.5, 10.0	0.0, 10.0	0.1, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	64	109	
Mean (StdDev)	5.33 (1.409)	6.78 (2.450)	6.42 (1.948)	6.22 (2.184)	
Median	6.00	7.04	6.33	6.15	
Min, Max	3.7, 6.3	1.0, 10.0	2.3, 10.0	0.1, 10.0	
C2D1 CFB					
n	3	10	64	109	
LS Mean (StdErr) [2]	-0.40 (0.464)	-0.65 (0.411)	-0.43 (0.176)	-0.71 (0.143)	
95% CI [2]	-1.45, 0.65	-1.58, 0.28	-0.77, -0.08	-0.99, -0.43	
Difference (95% CI) in CFB [2]		-0.25 (-1.45, 0.95)		-0.28 (-0.67, 0.11)	
p-value [3]		0.651		0.154	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	8	64	109	
Mean (StdDev)	5.79 (1.615)	5.95 (2.507)	6.05 (2.297)	5.81 (2.302)	
Median	6.00	5.57	6.00	5.79	
Min, Max	4.1, 7.3	1.8, 10.0	0.3, 10.0	0.2, 10.0	
C3D1 CFB					
n	3	8	64	109	
LS Mean (StdErr) [2]	0.24 (0.529)	-0.91 (0.467)	-0.81 (0.227)	-1.12 (0.184)	
95% CI [2]	-1.01, 1.49	-2.01, 0.20	-1.26, -0.36	-1.49, -0.76	
Difference (95% CI) in CFB [2]		-1.15 (-2.58, 0.29)		-0.31 (-0.81, 0.19)	
p-value [3]		0.102		0.217	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	3	9	61	108	
Mean (StdDev)	5.05 (1.078)	5.32 (2.525)	5.87 (2.428)	5.54 (2.484)	
Median	5.00	4.79	6.00	5.58	
Min, Max	4.0, 6.2	1.1, 10.0	0.2, 10.0	0.0, 10.0	
C4D1 CFB					
n	3	9	61	108	
LS Mean (StdErr) [2]	-0.81 (0.572)	-2.22 (0.506)	-0.94 (0.282)	-1.36 (0.224)	
95% CI [2]	-2.13, 0.51	-3.39, -1.05	-1.50, -0.38	-1.80, -0.92	
Difference (95% CI) in CFB [2]		-1.41 (-2.92, 0.10)		-0.42 (-1.03, 0.20)	
p-value [3]		0.064		0.180	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	9	60	110	
Mean (StdDev)	4.48 (1.437)	5.20 (2.415)	5.77 (2.452)	5.49 (2.460)	
Median	4.31	5.00	5.68	5.69	
Min, Max	3.1, 6.0	1.4, 10.0	0.6, 10.0	0.0, 10.0	
C5D1 CFB					
n	3	9	60	110	
LS Mean (StdErr) [2]	-1.45 (0.617)	-2.41 (0.545)	-0.96 (0.289)	-1.31 (0.224)	
95% CI [2]	-2.87, -0.02	-3.66, -1.15	-1.53, -0.39	-1.75, -0.87	
Difference (95% CI) in CFB [2]		-0.96 (-2.59, 0.67)		-0.35 (-0.98, 0.28)	
p-value [3]		0.211		0.269	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

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[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	59	109	
Mean (StdDev)	4.52 (1.278)	5.17 (2.908)	5.86 (2.417)	5.20 (2.714)	
Median	3.79	5.00	6.00	5.17	
Min, Max	3.8, 6.0	0.0, 10.0	0.4, 10.0	0.0, 10.0	
C6D1 CFB					
n	3	9	59	109	
LS Mean (StdErr) [2]	-1.49 (0.733)	-2.62 (0.648)	-0.80 (0.311)	-1.55 (0.240)	
95% CI [2]	-3.18, 0.20	-4.11, -1.12	-1.41, -0.18	-2.03, -1.08	
Difference (95% CI) in CFB [2]		-1.13 (-3.06, 0.81)		-0.76 (-1.44, -0.08)	
p-value [3]		0.217		0.029	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Fatigue Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	9	59	106	
Mean (StdDev)	4.60 (1.031)	4.94 (2.938)	5.82 (2.532)	5.05 (2.620)	
Median	4.00	4.86	5.78	5.14	
Min, Max	4.0, 5.8	0.0, 10.0	0.2, 10.0	0.0, 10.0	
C7D1 CFB					
n	3	9	59	106	
LS Mean (StdErr) [2]	-1.43 (0.774)	-2.83 (0.684)	-0.84 (0.313)	-1.65 (0.244)	
95% CI [2]	-3.21, 0.36	-4.41, -1.25	-1.45, -0.22	-2.14, -1.17	
Difference (95% CI) in CFB [2]		-1.40 (-3.45, 0.64)		-0.82 (-1.50, -0.13)	
Hedges'G (95% CI) in CFB		-0.67 (-2.36, 0.69)		-0.33 (-0.66, -0.01)	
p-value [3]		0.153		0.020	
					0.804

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	64	113	
Mean (StdDev)	4.36 (2.726)	4.01 (2.824)	3.68 (2.796)	3.96 (2.828)	
Median	5.79	4.09	3.04	4.00	
Min, Max	1.2, 6.1	0.0, 8.2	0.0, 9.3	0.0, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	64	109	
Mean (StdDev)	3.17 (2.716)	3.61 (2.623)	3.21 (2.697)	3.35 (2.682)	
Median	3.07	3.47	2.79	3.00	
Min, Max	0.5, 5.9	0.0, 8.3	0.0, 8.7	0.0, 10.0	
C2D1 CFB					
n	3	10	64	109	
LS Mean (StdErr) [2]	-1.04 (0.805)	-0.07 (0.712)	-0.45 (0.198)	-0.63 (0.161)	
95% CI [2]	-2.86, 0.78	-1.68, 1.54	-0.84, -0.06	-0.94, -0.31	
Difference (95% CI) in CFB [2]		0.98 (-1.10, 3.06)		-0.18 (-0.61, 0.26)	
p-value [3]		0.316		0.425	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	8	64	109	
Mean (StdDev)	4.02 (3.494)	3.08 (2.841)	2.83 (2.550)	2.96 (2.704)	
Median	5.79	2.46	2.18	2.29	
Min, Max	0.0, 6.3	0.0, 7.9	0.0, 8.1	0.0, 10.0	
C3D1 CFB					
n	3	8	64	109	
LS Mean (StdErr) [2]	-0.26 (1.022)	-0.82 (0.902)	-0.77 (0.230)	-0.95 (0.187)	
95% CI [2]	-2.68, 2.15	-2.95, 1.31	-1.23, -0.32	-1.32, -0.58	
Difference (95% CI) in CFB [2]		-0.56 (-3.33, 2.22)		-0.18 (-0.69, 0.33)	
p-value [3]		0.650		0.490	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	3	9	61	108	
Mean (StdDev)	3.38 (3.385)	2.76 (2.480)	3.04 (2.643)	2.91 (2.778)	
Median	3.36	2.54	2.50	2.08	
Min, Max	0.0, 6.8	0.0, 7.5	0.0, 9.9	0.0, 10.0	
C4D1 CFB					
n	3	9	61	108	
LS Mean (StdErr) [2]	-1.08 (1.238)	-1.45 (1.094)	-0.56 (0.281)	-0.98 (0.223)	
95% CI [2]	-3.94, 1.77	-3.97, 1.08	-1.11, -0.01	-1.42, -0.54	
Difference (95% CI) in CFB [2]		-0.36 (-3.63, 2.91)		-0.42 (-1.03, 0.19)	
p-value [3]		0.805		0.175	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	9	60	110	
Mean (StdDev)	2.85 (3.350)	2.55 (2.615)	3.07 (2.599)	2.74 (2.678)	
Median	2.00	1.69	2.37	2.00	
Min, Max	0.0, 6.5	0.0, 7.8	0.0, 9.6	0.0, 10.0	
C5D1 CFB					
n	3	9	60	110	
LS Mean (StdErr) [2]	-1.82 (1.180)	-2.01 (1.043)	-0.44 (0.274)	-1.02 (0.212)	
95% CI [2]	-4.54, 0.90	-4.41, 0.40	-0.98, 0.10	-1.43, -0.60	
Difference (95% CI) in CFB [2]		-0.19 (-3.31, 2.93)		-0.58 (-1.18, 0.02)	
p-value [3]		0.892		0.057	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	59	109	
Mean (StdDev)	2.73 (3.347)	2.15 (2.341)	2.86 (2.591)	2.48 (2.591)	
Median	1.71	1.79	2.07	1.83	
Min, Max	0.0, 6.5	0.0, 7.1	0.0, 8.6	0.0, 10.0	
C6D1 CFB					
n	3	9	59	109	
LS Mean (StdErr) [2]	-1.85 (1.527)	-2.21 (1.350)	-0.68 (0.290)	-1.26 (0.224)	
95% CI [2]	-5.37, 1.67	-5.33, 0.90	-1.25, -0.10	-1.70, -0.82	
Difference (95% CI) in CFB [2]		-0.36 (-4.39, 3.67)		-0.58 (-1.22, 0.05)	
p-value [3]		0.842		0.071	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Dizziness Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	9	59	106	
Mean (StdDev)	2.62 (3.120)	2.22 (2.402)	2.88 (2.663)	2.49 (2.605)	
Median	1.79	1.36	2.00	1.86	
Min, Max	0.0, 6.1	0.0, 7.5	0.0, 10.0	0.0, 10.0	
C7D1 CFB					
n	3	9	59	106	
LS Mean (StdErr) [2]	-1.75 (1.648)	-1.70 (1.457)	-0.70 (0.301)	-1.24 (0.235)	
95% CI [2]	-5.55, 2.05	-5.06, 1.66	-1.29, -0.10	-1.70, -0.78	
Difference (95% CI) in CFB [2]		0.05 (-4.30, 4.41)		-0.54 (-1.20, 0.11)	
Hedges'G (95% CI) in CFB		0.01 (-1.47, 1.50)		-0.23 (-0.55, 0.09)	
p-value [3]		0.979		0.105	
					0.645

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	64	113	
Mean (StdDev)	4.71 (4.172)	6.00 (3.151)	5.25 (2.635)	5.64 (2.376)	
Median	6.21	6.46	5.22	5.71	
Min, Max	0.0, 7.9	0.0, 10.0	0.0, 10.0	0.0, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	64	109	
Mean (StdDev)	4.17 (3.613)	5.70 (3.263)	4.72 (2.618)	4.90 (2.637)	
Median	6.07	6.54	4.30	4.86	
Min, Max	0.0, 6.4	0.0, 10.0	0.0, 10.0	0.0, 10.0	
C2D1 CFB					
n	3	10	64	109	
LS Mean (StdErr) [2]	-0.79 (0.416)	-0.75 (0.368)	-0.47 (0.160)	-0.70 (0.130)	
95% CI [2]	-1.74, 0.15	-1.58, 0.08	-0.78, -0.15	-0.96, -0.44	
Difference (95% CI) in CFB [2]		0.05 (-1.03, 1.12)		-0.23 (-0.59, 0.12)	
p-value [3]		0.925		0.196	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	8	64	109	
Mean (StdDev)	4.52 (3.996)	5.88 (3.075)	4.49 (2.649)	4.52 (2.730)	
Median	6.00	6.07	4.15	4.46	
Min, Max	0.0, 7.6	0.0, 10.0	0.0, 10.0	0.0, 10.0	
C3D1 CFB					
n	3	8	64	109	
LS Mean (StdErr) [2]	-0.42 (0.790)	-0.83 (0.697)	-0.68 (0.198)	-1.06 (0.160)	
95% CI [2]	-2.28, 1.45	-2.48, 0.82	-1.07, -0.29	-1.38, -0.74	
Difference (95% CI) in CFB [2]		-0.42 (-2.56, 1.73)		-0.38 (-0.81, 0.06)	
p-value [3]		0.660		0.087	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	3	9	61	108	
Mean (StdDev)	3.62 (3.186)	4.46 (3.324)	4.33 (2.752)	4.40 (2.838)	
Median	4.86	3.86	4.14	4.24	
Min, Max	0.0, 6.0	0.0, 10.0	0.0, 10.0	0.0, 10.0	
C4D1 CFB					
n	3	9	61	108	
LS Mean (StdErr) [2]	-1.57 (1.004)	-2.12 (0.887)	-0.80 (0.246)	-1.15 (0.196)	
95% CI [2]	-3.89, 0.74	-4.17, -0.07	-1.29, -0.32	-1.54, -0.76	
Difference (95% CI) in CFB [2]		-0.55 (-3.20, 2.10)		-0.35 (-0.89, 0.19)	
p-value [3]		0.646		0.202	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	9	60	110	
Mean (StdDev)	3.09 (2.938)	4.25 (3.296)	4.13 (2.781)	4.37 (2.861)	
Median	3.43	4.00	3.80	4.57	
Min, Max	0.0, 5.8	0.0, 10.0	0.0, 10.0	0.0, 10.0	
C5D1 CFB					
n	3	9	60	110	
LS Mean (StdErr) [2]	-2.28 (0.924)	-2.62 (0.816)	-0.87 (0.266)	-1.06 (0.206)	
95% CI [2]	-4.41, -0.15	-4.50, -0.74	-1.40, -0.35	-1.46, -0.65	
Difference (95% CI) in CFB [2]		-0.34 (-2.78, 2.10)		-0.18 (-0.76, 0.39)	
p-value [3]		0.754		0.531	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

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[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	59	109	
Mean (StdDev)	3.33 (3.055)	4.09 (3.279)	4.21 (2.719)	4.19 (2.926)	
Median	4.00	4.57	3.86	4.07	
Min, Max	0.0, 6.0	0.0, 10.0	0.0, 10.0	0.0, 10.0	
C6D1 CFB					
n	3	9	59	109	
LS Mean (StdErr) [2]	-2.15 (1.017)	-3.00 (0.899)	-0.71 (0.259)	-1.21 (0.200)	
95% CI [2]	-4.49, 0.20	-5.07, -0.92	-1.22, -0.20	-1.61, -0.82	
Difference (95% CI) in CFB [2]		-0.85 (-3.53, 1.84)		-0.50 (-1.07, 0.07)	
p-value [3]		0.487		0.084	

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Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Brain Fog Severity

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	9	59	106	
Mean (StdDev)	3.33 (2.992)	4.01 (3.304)	4.23 (2.840)	4.13 (2.960)	
Median	4.21	4.36	3.79	4.29	
Min, Max	0.0, 5.8	0.0, 10.0	0.0, 10.0	0.0, 10.0	
C7D1 CFB					
n	3	9	59	106	
LS Mean (StdErr) [2]	-2.11 (1.062)	-3.00 (0.939)	-0.73 (0.272)	-1.27 (0.212)	
95% CI [2]	-4.56, 0.34	-5.16, -0.84	-1.27, -0.19	-1.69, -0.85	
Difference (95% CI) in CFB [2]		-0.89 (-3.70, 1.91)		-0.54 (-1.14, 0.05)	
Hedges'G (95% CI) in CFB		-0.31 (-1.88, 1.10)		-0.25 (-0.58, 0.07)	
p-value [3]		0.485		0.074	
					0.813

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	64	113	
Mean (StdDev)	4.02 (2.688)	5.59 (2.328)	4.26 (2.727)	4.21 (2.466)	
Median	4.93	4.99	4.43	4.00	
Min, Max	1.0, 6.1	2.2, 8.4	0.0, 9.9	0.0, 9.9	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

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[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	64	109	
Mean (StdDev)	3.10 (2.873)	5.10 (2.097)	3.96 (2.593)	3.60 (2.414)	
Median	2.29	5.11	3.93	3.36	
Min, Max	0.7, 6.3	1.9, 7.6	0.0, 9.1	0.0, 10.0	
C2D1 CFB					
n	3	10	64	109	
LS Mean (StdErr) [2]	-1.27 (0.299)	-1.13 (0.265)	-0.28 (0.181)	-0.59 (0.147)	
95% CI [2]	-1.94, -0.59	-1.73, -0.53	-0.64, 0.08	-0.88, -0.30	
Difference (95% CI) in CFB [2]		0.13 (-0.64, 0.91)		-0.31 (-0.71, 0.09)	
p-value [3]		0.702		0.123	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

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[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

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[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Headache Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	8	64	109	
Mean (StdDev)	2.44 (3.049)	5.25 (2.172)	3.61 (2.555)	3.22 (2.355)	
Median	1.07	5.32	3.18	2.64	
Min, Max	0.3, 5.9	2.5, 8.3	0.0, 9.1	0.0, 10.0	
C3D1 CFB					
n	3	8	64	109	
LS Mean (StdErr) [2]	-1.83 (0.583)	-0.89 (0.515)	-0.55 (0.232)	-0.89 (0.188)	
95% CI [2]	-3.21, -0.45	-2.11, 0.33	-1.00, -0.09	-1.26, -0.52	
Difference (95% CI) in CFB [2]		0.94 (-0.64, 2.53)		-0.34 (-0.85, 0.17)	
p-value [3]		0.202		0.190	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	3	9	61	108	
Mean (StdDev)	1.89 (3.030)	4.45 (1.928)	3.71 (2.436)	3.11 (2.367)	
Median	0.29	3.79	3.36	2.75	
Min, Max	0.0, 5.4	2.1, 7.4	0.0, 8.4	0.0, 9.9	
C4D1 CFB					
n	3	9	61	108	
LS Mean (StdErr) [2]	-2.70 (0.418)	-2.32 (0.369)	-0.51 (0.260)	-1.00 (0.206)	
95% CI [2]	-3.67, -1.74	-3.17, -1.47	-1.03, 0.00	-1.41, -0.59	
Difference (95% CI) in CFB [2]		0.38 (-0.72, 1.49)		-0.49 (-1.05, 0.08)	
p-value [3]		0.446		0.091	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	9	60	110	
Mean (StdDev)	2.29 (2.704)	3.59 (1.627)	3.63 (2.472)	3.06 (2.395)	
Median	1.50	3.64	3.39	2.55	
Min, Max	0.1, 5.3	1.7, 6.8	0.0, 9.1	0.0, 10.0	
C5D1 CFB					
n	3	9	60	110	
LS Mean (StdErr) [2]	-2.10 (0.546)	-2.79 (0.482)	-0.71 (0.261)	-1.12 (0.202)	
95% CI [2]	-3.35, -0.84	-3.90, -1.68	-1.22, -0.19	-1.52, -0.73	
Difference (95% CI) in CFB [2]		-0.69 (-2.14, 0.75)		-0.42 (-0.99, 0.15)	
p-value [3]		0.299		0.148	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	59	109	
Mean (StdDev)	1.96 (2.975)	3.25 (1.603)	3.35 (2.457)	2.80 (2.483)	
Median	0.50	2.71	2.86	2.08	
Min, Max	0.0, 5.4	1.6, 6.2	0.0, 8.9	0.0, 10.0	
C6D1 CFB					
n	3	9	59	109	
LS Mean (StdErr) [2]	-2.72 (0.482)	-3.63 (0.426)	-0.82 (0.265)	-1.32 (0.205)	
95% CI [2]	-3.83, -1.61	-4.62, -2.65	-1.35, -0.30	-1.73, -0.92	
Difference (95% CI) in CFB [2]		-0.92 (-2.19, 0.36)		-0.50 (-1.08, 0.08)	
p-value [3]		0.136		0.091	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Headache Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	9	59	106	
Mean (StdDev)	1.98 (2.660)	3.73 (1.687)	3.40 (2.614)	2.73 (2.428)	
Median	0.93	3.09	2.86	2.04	
Min, Max	0.0, 5.0	1.9, 7.2	0.0, 8.9	0.0, 10.0	
C7D1 CFB					
n	3	9	59	106	
LS Mean (StdErr) [2]	-2.54 (0.630)	-2.87 (0.557)	-0.79 (0.265)	-1.37 (0.207)	
95% CI [2]	-3.99, -1.09	-4.15, -1.58	-1.31, -0.27	-1.77, -0.96	
Difference (95% CI) in CFB [2]		-0.32 (-1.99, 1.34)		-0.58 (-1.16, 0.00)	
Hedges'G (95% CI) in CFB		-0.19 (-1.73, 1.25)		-0.27 (-0.60, 0.04)	
p-value [3]		0.665		0.051	
					0.584

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	64	113	
Mean (StdDev)	1.12 (0.536)	1.87 (1.459)	1.56 (1.529)	1.50 (1.730)	
Median	1.14	1.57	1.19	1.00	
Min, Max	0.6, 1.6	0.0, 4.6	0.0, 7.2	0.0, 12.2	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	64	109	
Mean (StdDev)	0.62 (0.165)	1.56 (1.267)	1.30 (1.311)	1.13 (1.490)	
Median	0.71	1.39	0.75	0.69	
Min, Max	0.4, 0.7	0.0, 3.7	0.0, 4.9	0.0, 10.7	
C2D1 CFB					
n	3	10	64	109	
LS Mean (StdErr) [2]	-0.48 (0.612)	-0.28 (0.542)	-0.36 (0.122)	-0.47 (0.099)	
95% CI [2]	-1.86, 0.91	-1.51, 0.94	-0.60, -0.12	-0.66, -0.27	
Difference (95% CI) in CFB [2]		0.20 (-1.39, 1.78)		-0.11 (-0.38, 0.16)	
p-value [3]		0.786		0.406	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	8	64	109	
Mean (StdDev)	0.71 (0.500)	0.76 (0.915)	1.20 (1.192)	1.06 (1.240)	
Median	0.69	0.29	0.79	0.79	
Min, Max	0.2, 1.2	0.0, 2.3	0.0, 4.4	0.0, 5.8	
C3D1 CFB					
n	3	8	64	109	
LS Mean (StdErr) [2]	-0.42 (0.734)	-1.15 (0.648)	-0.48 (0.160)	-0.55 (0.130)	
95% CI [2]	-2.15, 1.32	-2.68, 0.38	-0.79, -0.16	-0.81, -0.30	
Difference (95% CI) in CFB [2]		-0.73 (-2.73, 1.26)		-0.08 (-0.43, 0.28)	
p-value [3]		0.413		0.666	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
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Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	3	9	61	108	
Mean (StdDev)	0.59 (0.386)	0.82 (0.907)	1.20 (1.162)	1.07 (1.461)	
Median	0.77	0.57	0.77	0.54	
Min, Max	0.1, 0.8	0.0, 2.8	0.0, 4.8	0.0, 9.0	
C4D1 CFB					
n	3	9	61	108	
LS Mean (StdErr) [2]	-0.61 (0.652)	-1.21 (0.576)	-0.47 (0.156)	-0.50 (0.124)	
95% CI [2]	-2.11, 0.90	-2.54, 0.12	-0.78, -0.16	-0.75, -0.26	
Difference (95% CI) in CFB [2]		-0.60 (-2.32, 1.12)		-0.03 (-0.37, 0.31)	
p-value [3]		0.444		0.844	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	9	60	110	
Mean (StdDev)	0.45 (0.108)	0.78 (0.670)	1.19 (1.216)	1.05 (1.546)	
Median	0.38	0.82	0.78	0.50	
Min, Max	0.4, 0.6	0.0, 1.9	0.0, 4.8	0.0, 9.6	
C5D1 CFB					
n	3	9	60	110	
LS Mean (StdErr) [2]	-0.66 (0.663)	-1.08 (0.586)	-0.53 (0.178)	-0.58 (0.138)	
95% CI [2]	-2.18, 0.87	-2.43, 0.28	-0.88, -0.18	-0.85, -0.31	
Difference (95% CI) in CFB [2]		-0.42 (-2.17, 1.33)		-0.05 (-0.44, 0.34)	
p-value [3]		0.596		0.805	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	59	109	
Mean (StdDev)	0.42 (0.105)	0.80 (0.870)	1.13 (1.317)	0.99 (1.351)	
Median	0.36	0.50	0.67	0.50	
Min, Max	0.4, 0.5	0.0, 2.3	0.0, 6.5	0.0, 9.0	
C6D1 CFB					
n	3	9	59	109	
LS Mean (StdErr) [2]	-0.63 (0.522)	-0.96 (0.462)	-0.50 (0.153)	-0.58 (0.118)	
95% CI [2]	-1.84, 0.57	-2.02, 0.11	-0.81, -0.20	-0.82, -0.35	
Difference (95% CI) in CFB [2]		-0.33 (-1.71, 1.05)		-0.08 (-0.41, 0.25)	
p-value [3]		0.600		0.638	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Count	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	9	59	106	
Mean (StdDev)	0.75 (0.669)	0.78 (0.950)	1.09 (1.286)	0.88 (1.126)	
Median	0.54	0.21	0.50	0.33	
Min, Max	0.2, 1.5	0.0, 2.4	0.0, 5.9	0.0, 4.8	
C7D1 CFB					
n	3	9	59	106	
LS Mean (StdErr) [2]	-0.28 (0.597)	-0.98 (0.528)	-0.50 (0.166)	-0.61 (0.129)	
95% CI [2]	-1.66, 1.10	-2.20, 0.24	-0.83, -0.18	-0.86, -0.35	
Difference (95% CI) in CFB [2]		-0.70 (-2.27, 0.88)		-0.10 (-0.47, 0.26)	
Hedges'G (95% CI) in CFB		-0.43 (-2.04, 0.96)		-0.08 (-0.40, 0.24)	
p-value [3]		0.337		0.579	
					0.407

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	64	113	
Mean (StdDev)	2.90 (2.990)	3.76 (2.808)	3.20 (2.638)	2.99 (2.389)	
Median	1.21	3.36	2.60	2.50	
Min, Max	1.1, 6.4	0.0, 9.5	0.0, 9.5	0.0, 9.4	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	64	109	
Mean (StdDev)	2.19 (2.499)	3.35 (2.550)	2.48 (2.429)	2.30 (2.338)	
Median	1.36	2.57	1.85	1.43	
Min, Max	0.2, 5.0	0.0, 6.4	0.0, 9.1	0.0, 8.9	
C2D1 CFB					
n	3	10	64	109	
LS Mean (StdErr) [2]	-0.29 (1.434)	0.46 (1.268)	-0.65 (0.192)	-0.66 (0.156)	
95% CI [2]	-3.54, 2.95	-2.41, 3.32	-1.03, -0.27	-0.97, -0.35	
Difference (95% CI) in CFB [2]		0.75 (-2.96, 4.46)		-0.01 (-0.43, 0.41)	
p-value [3]		0.659		0.966	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	8	64	109	
Mean (StdDev)	1.18 (0.491)	2.11 (2.277)	2.39 (2.334)	2.18 (2.241)	
Median	1.43	1.32	1.58	1.50	
Min, Max	0.6, 1.5	0.0, 5.1	0.0, 8.7	0.0, 9.5	
C3D1 CFB					
n	3	8	64	109	
LS Mean (StdErr) [2]	-1.54 (1.626)	-1.23 (1.436)	-0.69 (0.241)	-0.72 (0.195)	
95% CI [2]	-5.39, 2.30	-4.63, 2.16	-1.16, -0.21	-1.11, -0.34	
Difference (95% CI) in CFB [2]		0.31 (-4.11, 4.73)		-0.03 (-0.56, 0.50)	
p-value [3]		0.873		0.901	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	3	9	61	108	
Mean (StdDev)	1.76 (2.275)	2.21 (2.206)	2.57 (2.376)	2.08 (2.333)	
Median	0.54	2.15	2.14	1.23	
Min, Max	0.4, 4.4	0.0, 6.2	0.0, 8.3	0.0, 8.9	
C4D1 CFB					
n	3	9	61	108	
LS Mean (StdErr) [2]	-1.07 (1.300)	-1.48 (1.149)	-0.58 (0.244)	-0.80 (0.194)	
95% CI [2]	-4.06, 1.93	-4.13, 1.17	-1.07, -0.10	-1.19, -0.42	
Difference (95% CI) in CFB [2]		-0.41 (-3.85, 3.02)		-0.22 (-0.75, 0.31)	
p-value [3]		0.789		0.417	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	9	60	110	
Mean (StdDev)	1.23 (0.933)	1.84 (1.513)	2.53 (2.419)	2.02 (2.305)	
Median	1.07	1.31	1.61	1.15	
Min, Max	0.4, 2.2	0.0, 4.1	0.0, 8.5	0.0, 9.0	
C5D1 CFB					
n	3	9	60	110	
LS Mean (StdErr) [2]	-1.30 (1.283)	-1.23 (1.134)	-0.73 (0.275)	-0.95 (0.213)	
95% CI [2]	-4.26, 1.66	-3.84, 1.39	-1.27, -0.19	-1.37, -0.53	
Difference (95% CI) in CFB [2]		0.08 (-3.31, 3.47)		-0.22 (-0.82, 0.38)	
p-value [3]		0.959		0.465	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	59	109	
Mean (StdDev)	1.36 (1.624)	1.89 (2.065)	2.34 (2.402)	1.93 (2.253)	
Median	0.57	1.21	1.50	1.14	
Min, Max	0.3, 3.2	0.0, 5.5	0.0, 8.6	0.0, 8.9	
C6D1 CFB					
n	3	9	59	109	
LS Mean (StdErr) [2]	-1.19 (0.983)	-1.22 (0.868)	-0.69 (0.263)	-0.95 (0.204)	
95% CI [2]	-3.46, 1.07	-3.22, 0.79	-1.21, -0.17	-1.35, -0.55	
Difference (95% CI) in CFB [2]		-0.02 (-2.62, 2.57)		-0.26 (-0.84, 0.31)	
p-value [3]		0.984		0.368	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.3.2.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Diarrhea Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	9	59	106	
Mean (StdDev)	1.27 (0.725)	1.77 (2.085)	2.32 (2.525)	1.87 (2.283)	
Median	1.50	0.50	1.36	0.78	
Min, Max	0.5, 1.9	0.0, 5.1	0.0, 8.6	0.0, 8.7	
C7D1 CFB					
n	3	9	59	106	
LS Mean (StdErr) [2]	-1.22 (1.323)	-1.26 (1.169)	-0.74 (0.283)	-1.00 (0.221)	
95% CI [2]	-4.27, 1.84	-3.96, 1.44	-1.30, -0.18	-1.44, -0.56	
Difference (95% CI) in CFB [2]		-0.04 (-3.54, 3.45)		-0.26 (-0.88, 0.36)	
Hedges'G (95% CI) in CFB		-0.01 (-1.50, 1.47)		-0.11 (-0.44, 0.21)	
p-value [3]		0.978		0.413	
					0.954

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

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Table 35.2.2.4.2.2.2a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	15	35	52	88	
Mean (StdDev)	8.10 (1.661)	7.28 (1.367)	8.02 (1.571)	8.17 (1.530)	
Median	8.21	7.23	7.91	8.25	
Min, Max	5.1, 10.0	4.5, 10.0	4.8, 10.0	4.4, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
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Table 35.2.2.4.2.2.2a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	15	34	52	85	
Mean (StdDev)	6.83 (2.346)	6.55 (1.500)	7.22 (1.989)	7.13 (2.002)	
Median	6.62	6.71	7.37	7.21	
Min, Max	2.5, 10.0	2.7, 9.2	1.6, 10.0	1.2, 10.0	
C2D1 CFB					
n	15	34	52	85	
LS Mean (StdErr) [2]	-1.35 (0.315)	-0.84 (0.215)	-0.87 (0.206)	-1.14 (0.180)	
95% CI [2]	-1.99, -0.72	-1.28, -0.41	-1.28, -0.46	-1.49, -0.78	
Difference (95% CI) in CFB [2]		0.51 (-0.20, 1.22)		-0.27 (-0.72, 0.18)	
p-value [3]		0.154		0.245	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
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Table 35.2.2.4.2.2.2a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	34	52	83	
Mean (StdDev)	6.85 (2.694)	5.97 (1.650)	7.06 (2.276)	6.42 (2.331)	
Median	8.00	6.18	7.23	7.00	
Min, Max	0.9, 10.0	2.6, 9.0	0.9, 10.0	0.6, 10.0	
C3D1 CFB					
n	15	34	52	83	
LS Mean (StdErr) [2]	-1.18 (0.428)	-1.29 (0.292)	-1.02 (0.276)	-1.84 (0.241)	
95% CI [2]	-2.04, -0.31	-1.88, -0.70	-1.56, -0.47	-2.32, -1.37	
Difference (95% CI) in CFB [2]		-0.12 (-1.08, 0.85)		-0.83 (-1.43, -0.22)	
p-value [3]		0.809		0.008	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-pp-sex-a.sas Date: 15:19/07AUG2023

Table 35.2.2.4.2.2.2a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	15	34	49	83	
Mean (StdDev)	6.60 (2.806)	5.77 (1.943)	7.07 (2.222)	5.98 (2.681)	
Median	8.00	5.80	7.14	6.29	
Min, Max	1.5, 10.0	1.4, 9.1	2.0, 10.0	0.0, 10.0	
C4D1 CFB					
n	15	34	49	83	
LS Mean (StdErr) [2]	-1.35 (0.493)	-1.43 (0.336)	-1.02 (0.332)	-2.31 (0.282)	
95% CI [2]	-2.34, -0.35	-2.10, -0.75	-1.68, -0.37	-2.86, -1.75	
Difference (95% CI) in CFB [2]		-0.08 (-1.19, 1.03)		-1.28 (-2.00, -0.57)	
p-value [3]		0.883		<0.001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-pp-sex-a.sas Date: 15:19/07AUG2023

Table 35.2.2.4.2.2.2a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	34	48	85	
Mean (StdDev)	6.63 (2.915)	5.53 (1.900)	6.87 (2.419)	5.93 (2.564)	
Median	8.00	5.77	6.96	6.00	
Min, Max	0.9, 10.0	1.1, 9.0	1.1, 10.0	0.0, 10.0	
C5D1 CFB					
n	15	34	48	85	
LS Mean (StdErr) [2]	-1.15 (0.507)	-1.55 (0.346)	-1.18 (0.345)	-2.25 (0.282)	
95% CI [2]	-2.17, -0.13	-2.25, -0.86	-1.86, -0.50	-2.81, -1.69	
Difference (95% CI) in CFB [2]		-0.40 (-1.54, 0.74)		-1.07 (-1.81, -0.33)	
p-value [3]		0.486		0.005	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-pp-sex-a.sas Date: 15:19/07AUG2023

Table 35.2.2.4.2.2.2a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	15	34	47	84	
Mean (StdDev)	6.73 (2.717)	5.23 (2.011)	6.85 (2.521)	5.80 (2.796)	
Median	8.00	5.55	7.07	5.89	
Min, Max	1.6, 10.0	0.2, 9.4	0.4, 10.0	0.0, 10.0	
C6D1 CFB					
n	15	34	47	84	
LS Mean (StdErr) [2]	-1.12 (0.499)	-1.87 (0.339)	-1.19 (0.373)	-2.40 (0.306)	
95% CI [2]	-2.12, -0.11	-2.55, -1.19	-1.93, -0.45	-3.01, -1.80	
Difference (95% CI) in CFB [2]		-0.75 (-1.88, 0.37)		-1.21 (-2.02, -0.41)	
p-value [3]		0.183		0.004	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-pp-sex-a.sas Date: 15:19/07AUG2023

Table 35.2.2.4.2.2.2a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	15	34	47	81	
Mean (StdDev)	6.35 (2.864)	5.39 (1.871)	6.89 (2.554)	5.66 (2.843)	
Median	5.75	5.26	7.21	5.82	
Min, Max	1.4, 10.0	1.1, 9.0	0.2, 10.0	0.0, 10.0	
C7D1 CFB					
n	15	34	47	81	
LS Mean (StdErr) [2]	-1.57 (0.560)	-1.79 (0.382)	-1.19 (0.383)	-2.53 (0.315)	
95% CI [2]	-2.70, -0.44	-2.55, -1.02	-1.95, -0.44	-3.15, -1.91	
Difference (95% CI) in CFB [2]		-0.22 (-1.48, 1.05)		-1.34 (-2.16, -0.51)	
Hedges'G (95% CI) in CFB		-0.10 (-0.72, 0.52)		-0.48 (-0.86, -0.12)	
p-value [3]		0.732		0.002	
					0.148

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-pp-sex-a.sas Date: 15:19/07AUG2023

Table 35.2.2.4.2.2.3a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	32	52	35	71	
Mean (StdDev)	8.14 (1.498)	7.84 (1.629)	7.95 (1.666)	7.98 (1.470)	
Median	8.27	8.04	8.00	7.92	
Min, Max	5.3, 10.0	4.4, 10.0	4.8, 10.0	4.4, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-pp-reg-a.sas Date: 15:20/07AUG2023

Table 35.2.2.4.2.2.3a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	32	51	35	68	
Mean (StdDev)	7.20 (2.050)	7.08 (1.703)	7.07 (2.101)	6.87 (2.018)	
Median	7.10	7.27	7.31	6.86	
Min, Max	2.5, 10.0	3.0, 9.9	1.6, 10.0	1.2, 10.0	
C2D1 CFB					
n	32	51	35	68	
LS Mean (StdErr) [2]	-1.06 (0.209)	-0.89 (0.182)	-0.90 (0.264)	-1.16 (0.202)	
95% CI [2]	-1.48, -0.64	-1.25, -0.53	-1.43, -0.38	-1.56, -0.76	
Difference (95% CI) in CFB [2]		0.17 (-0.30, 0.64)		-0.26 (-0.84, 0.31)	
p-value [3]		0.475		0.370	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-pp-reg-a.sas Date: 15:20/07AUG2023

Table 35.2.2.4.2.2.3a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	32	50	35	67	
Mean (StdDev)	7.30 (2.374)	6.51 (2.003)	6.75 (2.342)	6.13 (2.268)	
Median	7.79	6.80	7.00	6.00	
Min, Max	0.9, 10.0	2.1, 10.0	0.9, 10.0	0.6, 10.0	
C3D1 CFB					
n	32	50	35	67	
LS Mean (StdErr) [2]	-0.91 (0.307)	-1.42 (0.267)	-1.12 (0.336)	-1.81 (0.257)	
95% CI [2]	-1.52, -0.29	-1.96, -0.89	-1.79, -0.46	-2.32, -1.30	
Difference (95% CI) in CFB [2]		-0.52 (-1.21, 0.17)		-0.69 (-1.42, 0.05)	
p-value [3]		0.141		0.066	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-pp-reg-a.sas Date: 15:20/07AUG2023

Table 35.2.2.4.2.2.3a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	30	50	34	67	
Mean (StdDev)	7.18 (2.445)	6.08 (2.338)	6.76 (2.295)	5.81 (2.597)	
Median	8.04	6.38	7.00	6.21	
Min, Max	1.5, 10.0	0.5, 10.0	2.0, 10.0	0.0, 10.0	
C4D1 CFB					
n	30	50	34	67	
LS Mean (StdErr) [2]	-1.22 (0.378)	-1.96 (0.316)	-0.96 (0.394)	-2.07 (0.299)	
95% CI [2]	-1.97, -0.47	-2.59, -1.33	-1.74, -0.17	-2.66, -1.48	
Difference (95% CI) in CFB [2]		-0.74 (-1.57, 0.09)		-1.11 (-1.97, -0.26)	
p-value [3]		0.082		0.011	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-pp-reg-a.sas Date: 15:20/07AUG2023

Table 35.2.2.4.2.2.3a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	29	51	34	68	
Mean (StdDev)	7.09 (2.715)	5.96 (2.112)	6.58 (2.363)	5.70 (2.593)	
Median	8.00	5.91	6.71	5.86	
Min, Max	0.9, 10.0	1.6, 10.0	1.1, 10.0	0.0, 10.0	
C5D1 CFB					
n	29	51	34	68	
LS Mean (StdErr) [2]	-1.27 (0.379)	-1.95 (0.304)	-1.03 (0.414)	-2.06 (0.312)	
95% CI [2]	-2.03, -0.52	-2.55, -1.34	-1.85, -0.21	-2.68, -1.45	
Difference (95% CI) in CFB [2]		-0.68 (-1.51, 0.16)		-1.03 (-1.93, -0.14)	
p-value [3]		0.110		0.024	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-pp-reg-a.sas Date: 15:20/07AUG2023

Table 35.2.2.4.2.2.3a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	28	50	34	68	
Mean (StdDev)	7.18 (2.589)	5.85 (2.368)	6.53 (2.513)	5.48 (2.763)	
Median	8.00	5.85	6.88	5.57	
Min, Max	1.6, 10.0	0.4, 10.0	0.4, 10.0	0.0, 10.0	
C6D1 CFB					
n	28	50	34	68	
LS Mean (StdErr) [2]	-1.17 (0.417)	-2.10 (0.335)	-1.13 (0.427)	-2.32 (0.320)	
95% CI [2]	-2.00, -0.33	-2.76, -1.43	-1.97, -0.28	-2.95, -1.68	
Difference (95% CI) in CFB [2]		-0.93 (-1.86, 0.00)		-1.19 (-2.12, -0.26)	
p-value [3]		0.050		0.012	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-pp-reg-a.sas Date: 15:20/07AUG2023

Table 35.2.2.4.2.2.3a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	29	49	33	66	
Mean (StdDev)	6.97 (2.826)	5.65 (2.286)	6.57 (2.450)	5.53 (2.808)	
Median	8.00	5.64	7.15	5.48	
Min, Max	1.2, 10.0	1.5, 10.0	0.2, 10.0	0.0, 10.0	
C7D1 CFB					
n	29	49	33	66	
LS Mean (StdErr) [2]	-1.45 (0.422)	-2.36 (0.348)	-1.10 (0.459)	-2.23 (0.340)	
95% CI [2]	-2.29, -0.61	-3.06, -1.67	-2.01, -0.19	-2.90, -1.55	
Difference (95% CI) in CFB [2]		-0.91 (-1.85, 0.03)		-1.13 (-2.12, -0.13)	
Hedges'G (95% CI) in CFB		-0.38 (-0.86, 0.08)		-0.41 (-0.85, 0.01)	
p-value [3]		0.057		0.027	
					0.798

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-pp-reg-a.sas Date: 15:20/07AUG2023

Table 35.2.2.4.2.2.4a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-pp-cou-a.sas Date: 15:21/07AUG2023

Table 35.2.2.4.2.2.4a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-pp-cou-a.sas Date: 15:21/07AUG2023

Table 35.2.2.4.2.2.4a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-pp-cou-a.sas Date: 15:21/07AUG2023

Table 35.2.2.4.2.2.4a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-pp-cou-a.sas Date: 15:21/07AUG2023

Table 35.2.2.4.2.2.4a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-pp-cou-a.sas Date: 15:21/07AUG2023

Table 35.2.2.4.2.2.5a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	22	37	45	86	
Mean (StdDev)	7.05 (1.647)	6.56 (1.125)	8.53 (1.309)	8.51 (1.300)	
Median	6.74	6.86	8.93	8.52	
Min, Max	4.8, 10.0	4.4, 8.8	5.5, 10.0	5.7, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-pp-ism-a.sas Date: 15:22/07AUG2023

Table 35.2.2.4.2.2.5a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	22	35	45	84	
Mean (StdDev)	6.37 (1.898)	5.69 (1.331)	7.50 (2.056)	7.49 (1.831)	
Median	6.50	6.07	7.93	7.56	
Min, Max	3.7, 10.0	2.1, 7.5	1.6, 10.0	1.2, 10.0	
C2D1 CFB					
n	22	35	45	84	
LS Mean (StdErr) [2]	-0.81 (0.253)	-0.99 (0.187)	-1.10 (0.215)	-1.12 (0.173)	
95% CI [2]	-1.32, -0.30	-1.37, -0.62	-1.52, -0.67	-1.46, -0.78	
Difference (95% CI) in CFB [2]		-0.18 (-0.73, 0.37)		-0.02 (-0.52, 0.47)	
p-value [3]		0.515		0.929	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-pp-ism-a.sas Date: 15:22/07AUG2023

Table 35.2.2.4.2.2.5a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	22	35	45	82	
Mean (StdDev)	6.13 (2.153)	4.91 (1.535)	7.45 (2.351)	6.88 (2.120)	
Median	6.23	4.93	8.00	7.32	
Min, Max	1.6, 10.0	2.1, 7.8	0.9, 10.0	0.6, 10.0	
C3D1 CFB					
n	22	35	45	82	
LS Mean (StdErr) [2]	-0.89 (0.343)	-1.68 (0.253)	-1.07 (0.288)	-1.64 (0.233)	
95% CI [2]	-1.58, -0.21	-2.19, -1.17	-1.64, -0.51	-2.10, -1.18	
Difference (95% CI) in CFB [2]		-0.78 (-1.53, -0.04)		-0.56 (-1.23, 0.10)	
p-value [3]		0.040		0.097	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-pp-ism-a.sas Date: 15:22/07AUG2023

Table 35.2.2.4.2.2.5a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	20	34	44	83	
Mean (StdDev)	5.92 (2.187)	4.52 (1.835)	7.43 (2.302)	6.50 (2.493)	
Median	6.08	4.71	8.11	6.54	
Min, Max	2.3, 10.0	1.1, 7.1	1.5, 10.0	0.0, 10.0	
C4D1 CFB					
n	20	34	44	83	
LS Mean (StdErr) [2]	-0.82 (0.391)	-1.95 (0.282)	-1.14 (0.344)	-2.05 (0.273)	
95% CI [2]	-1.60, -0.03	-2.52, -1.38	-1.82, -0.46	-2.59, -1.51	
Difference (95% CI) in CFB [2]		-1.13 (-1.99, -0.28)		-0.91 (-1.69, -0.13)	
p-value [3]		0.011		0.023	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-pp-ism-a.sas Date: 15:22/07AUG2023

Table 35.2.2.4.2.2.5a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	36	44	83	
Mean (StdDev)	5.62 (2.350)	4.62 (1.659)	7.33 (2.441)	6.33 (2.483)	
Median	5.32	5.00	8.00	6.55	
Min, Max	2.5, 10.0	1.1, 8.0	0.9, 10.0	0.0, 10.0	
C5D1 CFB					
n	19	36	44	83	
LS Mean (StdErr) [2]	-1.03 (0.360)	-1.79 (0.248)	-1.20 (0.361)	-2.18 (0.287)	
95% CI [2]	-1.75, -0.30	-2.29, -1.29	-1.92, -0.49	-2.75, -1.61	
Difference (95% CI) in CFB [2]		-0.76 (-1.55, 0.03)		-0.98 (-1.80, -0.16)	
p-value [3]		0.059		0.020	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-pp-ism-a.sas Date: 15:22/07AUG2023

Table 35.2.2.4.2.2.5a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	20	37	42	81	
Mean (StdDev)	5.88 (2.222)	4.39 (1.863)	7.27 (2.595)	6.21 (2.694)	
Median	5.64	4.85	8.00	6.71	
Min, Max	2.0, 10.0	0.2, 8.3	0.4, 10.0	0.0, 10.0	
C6D1 CFB					
n	20	37	42	81	
LS Mean (StdErr) [2]	-0.80 (0.392)	-2.05 (0.273)	-1.33 (0.389)	-2.38 (0.306)	
95% CI [2]	-1.58, -0.01	-2.60, -1.51	-2.10, -0.56	-2.98, -1.77	
Difference (95% CI) in CFB [2]		-1.26 (-2.11, -0.40)		-1.05 (-1.93, -0.16)	
p-value [3]		0.005		0.022	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-pp-ism-a.sas Date: 15:22/07AUG2023

Table 35.2.2.4.2.2.5a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	19	36	43	79	
Mean (StdDev)	5.85 (2.257)	4.43 (1.990)	7.16 (2.691)	6.10 (2.671)	
Median	5.46	4.96	8.00	6.00	
Min, Max	1.9, 10.0	1.1, 8.4	0.2, 10.0	0.0, 10.0	
C7D1 CFB					
n	19	36	43	79	
LS Mean (StdErr) [2]	-1.10 (0.443)	-2.12 (0.306)	-1.39 (0.396)	-2.43 (0.320)	
95% CI [2]	-1.99, -0.21	-2.73, -1.51	-2.18, -0.61	-3.07, -1.80	
Difference (95% CI) in CFB [2]		-1.02 (-1.99, -0.04)		-1.04 (-1.95, -0.13)	
Hedges'G (95% CI) in CFB		-0.54 (-1.14, 0.02)		-0.37 (-0.76, -0.00)	
p-value [3]		0.041		0.025	
					0.973

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-pp-ism-a.sas Date: 15:22/07AUG2023

Table 35.2.2.4.2.2.6a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	13	26	54	97	
Mean (StdDev)	7.74 (1.815)	7.95 (1.570)	8.11 (1.527)	7.91 (1.533)	
Median	7.93	7.75	8.00	7.93	
Min, Max	4.8, 10.0	5.0, 10.0	4.8, 10.0	4.4, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-pp-tryp-a.sas Date: 15:23/07AUG2023

Table 35.2.2.4.2.2.6a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	54	94	
Mean (StdDev)	6.22 (2.349)	6.98 (1.741)	7.35 (1.948)	6.96 (1.930)	
Median	6.07	6.79	7.71	7.00	
Min, Max	1.6, 9.9	3.3, 10.0	2.5, 10.0	1.2, 10.0	
C2D1 CFB					
n	13	25	54	94	
LS Mean (StdErr) [2]	-1.50 (0.468)	-1.06 (0.317)	-0.74 (0.162)	-0.94 (0.130)	
95% CI [2]	-2.45, -0.55	-1.70, -0.41	-1.06, -0.42	-1.19, -0.68	
Difference (95% CI) in CFB [2]		0.45 (-0.64, 1.54)		-0.20 (-0.59, 0.20)	
p-value [3]		0.410		0.333	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-pp-tryp-a.sas Date: 15:23/07AUG2023

Table 35.2.2.4.2.2.6a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	25	54	92	
Mean (StdDev)	6.26 (2.816)	6.64 (1.906)	7.19 (2.224)	6.20 (2.222)	
Median	7.07	6.69	7.57	6.46	
Min, Max	0.9, 10.0	2.3, 10.0	0.9, 10.0	0.6, 10.0	
C3D1 CFB					
n	13	25	54	92	
LS Mean (StdErr) [2]	-1.52 (0.588)	-1.42 (0.398)	-0.92 (0.221)	-1.73 (0.178)	
95% CI [2]	-2.71, -0.33	-2.23, -0.61	-1.36, -0.48	-2.08, -1.37	
Difference (95% CI) in CFB [2]		0.10 (-1.27, 1.47)		-0.81 (-1.35, -0.26)	
p-value [3]		0.884		0.004	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-pp-tryp-a.sas Date: 15:23/07AUG2023

Table 35.2.2.4.2.2.6a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	12	25	52	92	
Mean (StdDev)	6.13 (2.721)	6.36 (1.982)	7.15 (2.251)	5.80 (2.599)	
Median	5.55	6.29	7.41	6.22	
Min, Max	2.0, 9.7	2.1, 10.0	1.5, 10.0	0.0, 10.0	
C4D1 CFB					
n	12	25	52	92	
LS Mean (StdErr) [2]	-1.56 (0.637)	-1.65 (0.420)	-0.97 (0.272)	-2.16 (0.216)	
95% CI [2]	-2.85, -0.27	-2.50, -0.80	-1.51, -0.43	-2.58, -1.73	
Difference (95% CI) in CFB [2]		-0.09 (-1.57, 1.39)		-1.19 (-1.85, -0.52)	
p-value [3]		0.904		<0.001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-pp-tryp-a.sas Date: 15:23/07AUG2023

Table 35.2.2.4.2.2.6a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	26	51	93	
Mean (StdDev)	6.09 (2.806)	6.36 (1.958)	6.99 (2.450)	5.66 (2.489)	
Median	5.64	5.95	7.50	5.57	
Min, Max	1.1, 10.0	1.9, 10.0	0.9, 10.0	0.0, 10.0	
C5D1 CFB					
n	12	26	51	93	
LS Mean (StdErr) [2]	-1.51 (0.639)	-1.54 (0.410)	-1.16 (0.285)	-2.28 (0.221)	
95% CI [2]	-2.80, -0.21	-2.37, -0.71	-1.72, -0.60	-2.72, -1.85	
Difference (95% CI) in CFB [2]		-0.03 (-1.52, 1.45)		-1.12 (-1.81, -0.44)	
p-value [3]		0.965		0.001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-pp-tryp-a.sas Date: 15:23/07AUG2023

Table 35.2.2.4.2.2.6a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	26	50	92	
Mean (StdDev)	5.75 (3.139)	6.12 (2.175)	7.08 (2.348)	5.50 (2.702)	
Median	5.16	5.62	7.25	5.72	
Min, Max	0.4, 10.0	2.0, 10.0	1.6, 10.0	0.0, 10.0	
C6D1 CFB					
n	12	26	50	92	
LS Mean (StdErr) [2]	-1.88 (0.709)	-1.79 (0.455)	-1.00 (0.297)	-2.40 (0.229)	
95% CI [2]	-3.32, -0.44	-2.71, -0.87	-1.58, -0.41	-2.85, -1.95	
Difference (95% CI) in CFB [2]		0.09 (-1.56, 1.74)		-1.40 (-2.12, -0.68)	
p-value [3]		0.915		<0.001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-pp-tryp-a.sas Date: 15:23/07AUG2023

Table 35.2.2.4.2.2.6a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	12	25	50	90	
Mean (StdDev)	5.57 (3.424)	6.09 (2.204)	7.04 (2.339)	5.44 (2.680)	
Median	5.18	5.25	7.41	5.59	
Min, Max	0.2, 10.0	1.8, 10.0	1.4, 10.0	0.0, 10.0	
C7D1 CFB					
n	12	25	50	90	
LS Mean (StdErr) [2]	-2.20 (0.770)	-1.85 (0.500)	-1.07 (0.306)	-2.44 (0.238)	
95% CI [2]	-3.76, -0.63	-2.87, -0.83	-1.68, -0.47	-2.91, -1.97	
Difference (95% CI) in CFB [2]		0.35 (-1.46, 2.15)		-1.36 (-2.10, -0.62)	
Hedges'G (95% CI) in CFB		0.13 (-0.57, 0.86)		-0.61 (-0.97, -0.26)	
p-value [3]		0.699		<0.001	
					0.056

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-pp-tryp-a.sas Date: 15:23/07AUG2023

Table 35.2.2.4.2.2.7a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	63	114	4	9	
Mean (StdDev)	8.05 (1.546)	7.86 (1.531)	7.89 (2.323)	8.68 (1.453)	
Median	8.00	7.93	8.39	9.57	
Min, Max	4.8, 10.0	4.4, 10.0	4.8, 10.0	6.4, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-pp-ecog-a.sas Date: 15:24/07AUG2023

Table 35.2.2.4.2.2.7a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	63	110	4	9	
Mean (StdDev)	7.16 (2.080)	6.91 (1.875)	6.67 (1.954)	7.60 (1.991)	
Median	7.31	6.86	7.31	7.42	
Min, Max	1.6, 10.0	1.2, 10.0	3.9, 8.1	4.6, 10.0	
C2D1 CFB					
n	63	110	4	9	
LS Mean (StdErr) [2]	-0.97 (0.175)	-1.06 (0.142)	-0.67 (1.016)	-0.31 (0.805)	
95% CI [2]	-1.32, -0.63	-1.34, -0.78	-2.96, 1.63	-2.13, 1.51	
Difference (95% CI) in CFB [2]		-0.09 (-0.48, 0.30)		0.36 (-1.62, 2.34)	
p-value [3]		0.643		0.691	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-pp-ecog-a.sas Date: 15:24/07AUG2023

Table 35.2.2.4.2.2.7a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	63	108	4	9	
Mean (StdDev)	7.04 (2.362)	6.20 (2.104)	6.58 (2.556)	7.35 (2.639)	
Median	7.23	6.21	7.17	8.08	
Min, Max	0.9, 10.0	0.6, 10.0	3.1, 8.9	3.1, 10.0	
C3D1 CFB					
n	63	108	4	9	
LS Mean (StdErr) [2]	-1.01 (0.231)	-1.68 (0.187)	-0.95 (1.740)	-0.94 (1.379)	
95% CI [2]	-1.46, -0.55	-2.05, -1.31	-4.89, 2.99	-4.06, 2.18	
Difference (95% CI) in CFB [2]		-0.68 (-1.19, -0.16)		0.01 (-3.38, 3.41)	
p-value [3]		0.010		0.993	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-pp-ecog-a.sas Date: 15:24/07AUG2023

Table 35.2.2.4.2.2.7a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	60	108	4	9	
Mean (StdDev)	7.01 (2.351)	5.85 (2.423)	6.21 (2.672)	6.82 (3.145)	
Median	7.18	6.11	6.43	7.43	
Min, Max	1.5, 10.0	0.0, 10.0	3.1, 8.9	1.4, 10.0	
C4D1 CFB					
n	60	108	4	9	
LS Mean (StdErr) [2]	-1.03 (0.276)	-2.04 (0.218)	-1.13 (2.100)	-1.28 (1.664)	
95% CI [2]	-1.57, -0.48	-2.47, -1.61	-5.88, 3.62	-5.05, 2.48	
Difference (95% CI) in CFB [2]		-1.01 (-1.62, -0.41)		-0.15 (-4.25, 3.95)	
p-value [3]		0.001		0.935	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-pp-ecog-a.sas Date: 15:24/07AUG2023

Table 35.2.2.4.2.2.7a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	59	110	4	9	
Mean (StdDev)	6.90 (2.520)	5.72 (2.291)	5.59 (2.576)	7.01 (3.347)	
Median	7.21	5.68	5.69	8.00	
Min, Max	0.9, 10.0	0.0, 10.0	2.5, 8.5	1.1, 10.0	
C5D1 CFB					
n	59	110	4	9	
LS Mean (StdErr) [2]	-1.07 (0.283)	-2.06 (0.218)	-1.83 (2.226)	-1.35 (1.764)	
95% CI [2]	-1.63, -0.51	-2.49, -1.63	-6.87, 3.20	-5.34, 2.64	
Difference (95% CI) in CFB [2]		-0.99 (-1.61, -0.37)		0.48 (-3.86, 4.83)	
p-value [3]		0.002		0.808	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
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Table 35.2.2.4.2.2.7a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	58	109	4	9	
Mean (StdDev)	6.87 (2.580)	5.54 (2.525)	6.12 (2.192)	6.83 (3.313)	
Median	7.14	5.57	6.17	8.36	
Min, Max	0.4, 10.0	0.0, 10.0	3.6, 8.6	1.0, 10.0	
C6D1 CFB					
n	58	109	4	9	
LS Mean (StdErr) [2]	-1.10 (0.306)	-2.26 (0.235)	-1.37 (2.043)	-1.60 (1.619)	
95% CI [2]	-1.70, -0.50	-2.73, -1.80	-5.99, 3.25	-5.26, 2.07	
Difference (95% CI) in CFB [2]		-1.16 (-1.84, -0.49)		-0.23 (-4.21, 3.76)	
p-value [3]		<0.001		0.901	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-pp-ecog-a.sas Date: 15:24/07AUG2023

Table 35.2.2.4.2.2.7a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	59	106	3	9	
Mean (StdDev)	6.76 (2.659)	5.49 (2.510)	6.70 (2.038)	6.69 (3.363)	
Median	7.21	5.44	7.21	8.29	
Min, Max	0.2, 10.0	0.0, 10.0	4.5, 8.4	1.4, 10.0	
C7D1 CFB					
n	59	106	3	9	
LS Mean (StdErr) [2]	-1.21 (0.315)	-2.32 (0.247)	-1.54 (2.508)	-1.44 (1.825)	
95% CI [2]	-1.83, -0.59	-2.81, -1.83	-7.32, 4.24	-5.65, 2.77	
Difference (95% CI) in CFB [2]		-1.11 (-1.81, -0.41)		0.10 (-4.76, 4.96)	
Hedges'G (95% CI) in CFB		-0.44 (-0.77, -0.12)		0.02 (-1.46, 1.51)	
p-value [3]		0.002		0.964	
					0.363

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
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Table 35.2.2.4.2.2.8a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	64	113	
Mean (StdDev)	8.31 (0.599)	8.76 (1.494)	8.03 (1.611)	7.84 (1.522)	
Median	8.00	8.93	8.00	7.71	
Min, Max	7.9, 9.0	5.1, 10.0	4.8, 10.0	4.4, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-pp-thpy-a.sas Date: 15:25/07AUG2023

Table 35.2.2.4.2.2.8a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	64	109	
Mean (StdDev)	7.75 (1.221)	7.79 (1.454)	7.10 (2.095)	6.89 (1.906)	
Median	8.00	8.24	7.30	6.86	
Min, Max	6.4, 8.8	5.1, 10.0	1.6, 10.0	1.2, 10.0	
C2D1 CFB					
n	3	10	64	109	
LS Mean (StdErr) [2]	-0.59 (0.751)	-0.99 (0.664)	-0.98 (0.178)	-1.04 (0.145)	
95% CI [2]	-2.29, 1.11	-2.49, 0.52	-1.33, -0.63	-1.33, -0.76	
Difference (95% CI) in CFB [2]		-0.39 (-2.33, 1.55)		-0.06 (-0.45, 0.33)	
p-value [3]		0.658		0.760	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
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Table 35.2.2.4.2.2.8a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	8	64	109	
Mean (StdDev)	7.52 (0.502)	6.99 (1.990)	6.99 (2.407)	6.24 (2.169)	
Median	7.57	7.32	7.23	6.21	
Min, Max	7.0, 8.0	3.7, 10.0	0.9, 10.0	0.6, 10.0	
C3D1 CFB					
n	3	8	64	109	
LS Mean (StdErr) [2]	-0.65 (1.353)	-1.63 (1.195)	-1.04 (0.235)	-1.64 (0.191)	
95% CI [2]	-3.85, 2.55	-4.45, 1.20	-1.50, -0.58	-2.02, -1.27	
Difference (95% CI) in CFB [2]		-0.98 (-4.66, 2.69)		-0.60 (-1.12, -0.08)	
p-value [3]		0.547		0.023	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
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Table 35.2.2.4.2.2.8a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	3	9	61	108	
Mean (StdDev)	6.75 (1.666)	6.28 (2.050)	6.97 (2.395)	5.89 (2.521)	
Median	7.38	6.23	7.14	6.25	
Min, Max	4.9, 8.0	3.6, 10.0	1.5, 10.0	0.0, 10.0	
C4D1 CFB					
n	3	9	61	108	
LS Mean (StdErr) [2]	-1.67 (1.327)	-2.70 (1.173)	-1.01 (0.283)	-1.95 (0.225)	
95% CI [2]	-4.73, 1.39	-5.41, 0.00	-1.56, -0.45	-2.39, -1.50	
Difference (95% CI) in CFB [2]		-1.03 (-4.53, 2.48)		-0.94 (-1.56, -0.32)	
p-value [3]		0.518		0.003	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
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Table 35.2.2.4.2.2.8a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	9	60	110	
Mean (StdDev)	6.34 (2.529)	5.82 (2.206)	6.84 (2.542)	5.81 (2.417)	
Median	7.59	4.83	6.96	5.88	
Min, Max	3.4, 8.0	3.1, 10.0	0.9, 10.0	0.0, 10.0	
C5D1 CFB					
n	3	9	60	110	
LS Mean (StdErr) [2]	-2.22 (1.385)	-3.35 (1.224)	-1.05 (0.288)	-1.91 (0.223)	
95% CI [2]	-5.41, 0.98	-6.17, -0.52	-1.62, -0.48	-2.35, -1.47	
Difference (95% CI) in CFB [2]		-1.13 (-4.79, 2.53)		-0.85 (-1.48, -0.23)	
p-value [3]		0.497		0.008	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
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Table 35.2.2.4.2.2.8a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	59	109	
Mean (StdDev)	6.28 (2.057)	5.70 (2.323)	6.85 (2.581)	5.63 (2.630)	
Median	6.83	4.25	7.14	5.77	
Min, Max	4.0, 8.0	3.1, 10.0	0.4, 10.0	0.0, 10.0	
C6D1 CFB					
n	3	9	59	109	
LS Mean (StdErr) [2]	-2.35 (1.486)	-3.63 (1.313)	-1.05 (0.306)	-2.12 (0.237)	
95% CI [2]	-5.78, 1.07	-6.65, -0.60	-1.66, -0.45	-2.59, -1.65	
Difference (95% CI) in CFB [2]		-1.27 (-5.20, 2.65)		-1.07 (-1.74, -0.40)	
p-value [3]		0.476		0.002	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
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Table 35.2.2.4.2.2.8a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	9	59	106	
Mean (StdDev)	6.46 (1.987)	5.71 (2.080)	6.77 (2.659)	5.57 (2.635)	
Median	7.15	5.21	7.21	5.59	
Min, Max	4.2, 8.0	3.2, 10.0	0.2, 10.0	0.0, 10.0	
C7D1 CFB					
n	3	9	59	106	
LS Mean (StdErr) [2]	-1.96 (1.439)	-3.20 (1.272)	-1.19 (0.323)	-2.19 (0.252)	
95% CI [2]	-5.28, 1.36	-6.14, -0.27	-1.83, -0.55	-2.69, -1.69	
Difference (95% CI) in CFB [2]		-1.24 (-5.05, 2.56)		-1.00 (-1.71, -0.29)	
Hedges'G (95% CI) in CFB		-0.32 (-1.90, 1.09)		-0.39 (-0.72, -0.07)	
p-value [3]		0.472		0.006	
					0.888

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-pp-thpy-a.sas Date: 15:25/07AUG2023

Table 35.2.2.4.4.2.2a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	15	35	52	88	
Mean (StdDev)	19.70 (5.626)	16.81 (5.140)	19.16 (5.987)	19.06 (5.588)	
Median	20.71	15.57	18.71	18.54	
Min, Max	11.0, 30.0	8.8, 30.0	8.1, 30.0	8.6, 30.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-pp-sex-a.sas Date: 15:34/07AUG2023

Table 35.2.2.4.4.2.2a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	15	34	52	85	
Mean (StdDev)	16.97 (5.693)	14.52 (5.646)	17.13 (6.861)	15.49 (5.866)	
Median	16.79	13.04	16.68	15.14	
Min, Max	9.4, 29.2	5.8, 26.8	4.6, 29.8	3.5, 30.0	
C2D1 CFB					
n	15	34	52	85	
LS Mean (StdErr) [2]	-3.17 (0.817)	-2.71 (0.558)	-1.90 (0.607)	-3.49 (0.528)	
95% CI [2]	-4.82, -1.52	-3.84, -1.59	-3.09, -0.70	-4.54, -2.45	
Difference (95% CI) in CFB [2]		0.46 (-1.39, 2.30)		-1.60 (-2.92, -0.27)	
p-value [3]		0.621		0.018	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-pp-sex-a.sas Date: 15:34/07AUG2023

Table 35.2.2.4.4.2.2a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	34	52	83	
Mean (StdDev)	16.60 (7.378)	13.10 (5.441)	16.61 (7.022)	13.69 (6.477)	
Median	18.77	11.61	16.26	12.86	
Min, Max	3.7, 28.9	2.7, 24.1	4.5, 29.4	1.5, 30.0	
C3D1 CFB					
n	15	34	52	83	
LS Mean (StdErr) [2]	-3.09 (1.021)	-3.78 (0.697)	-2.14 (0.744)	-5.08 (0.648)	
95% CI [2]	-5.15, -1.04	-5.19, -2.38	-3.61, -0.67	-6.37, -3.80	
Difference (95% CI) in CFB [2]		-0.69 (-2.99, 1.61)		-2.94 (-4.57, -1.31)	
p-value [3]		0.548		<0.001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-pp-sex-a.sas Date: 15:34/07AUG2023

Table 35.2.2.4.4.2.2a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	15	34	49	83	
Mean (StdDev)	15.70 (7.264)	12.51 (5.965)	16.49 (7.089)	12.59 (6.838)	
Median	15.07	11.79	17.64	11.50	
Min, Max	4.1, 29.7	1.8, 24.5	3.8, 29.6	0.7, 29.9	
C4D1 CFB					
n	15	34	49	83	
LS Mean (StdErr) [2]	-3.82 (1.239)	-4.23 (0.846)	-2.52 (0.854)	-6.30 (0.725)	
95% CI [2]	-6.31, -1.32	-5.94, -2.53	-4.21, -0.83	-7.73, -4.86	
Difference (95% CI) in CFB [2]		-0.42 (-3.21, 2.38)		-3.78 (-5.62, -1.95)	
p-value [3]		0.765		<0.0001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-pp-sex-a.sas Date: 15:34/07AUG2023

Table 35.2.2.4.4.2.2a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	34	48	85	
Mean (StdDev)	16.26 (7.228)	11.95 (5.795)	16.12 (7.438)	12.22 (6.886)	
Median	17.14	11.78	15.85	10.86	
Min, Max	5.1, 29.9	1.9, 25.2	1.7, 30.0	0.3, 30.0	
C5D1 CFB					
n	15	34	48	85	
LS Mean (StdErr) [2]	-3.02 (1.244)	-4.61 (0.849)	-3.01 (0.941)	-6.63 (0.769)	
95% CI [2]	-5.53, -0.52	-6.32, -2.90	-4.88, -1.15	-8.15, -5.11	
Difference (95% CI) in CFB [2]		-1.59 (-4.39, 1.22)		-3.62 (-5.63, -1.60)	
p-value [3]		0.260		<0.001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-pp-sex-a.sas Date: 15:34/07AUG2023

Table 35.2.2.4.4.2.2a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	15	34	47	84	
Mean (StdDev)	16.47 (6.839)	11.44 (5.180)	15.62 (7.635)	11.66 (7.267)	
Median	17.46	11.02	15.86	10.82	
Min, Max	5.6, 29.6	2.6, 22.4	0.5, 30.0	0.1, 30.0	
C6D1 CFB					
n	15	34	47	84	
LS Mean (StdErr) [2]	-3.03 (1.254)	-5.27 (0.853)	-3.24 (1.007)	-7.10 (0.826)	
95% CI [2]	-5.55, -0.50	-6.99, -3.55	-5.23, -1.25	-8.74, -5.47	
Difference (95% CI) in CFB [2]		-2.25 (-5.07, 0.58)		-3.86 (-6.04, -1.68)	
p-value [3]		0.117		<0.001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-pp-sex-a.sas Date: 15:34/07AUG2023

Table 35.2.2.4.4.2.2a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	15	34	47	81	
Mean (StdDev)	16.62 (7.177)	11.40 (5.238)	15.85 (7.391)	11.34 (7.161)	
Median	16.93	10.82	16.14	10.00	
Min, Max	6.0, 30.0	2.4, 22.5	0.5, 30.0	0.0, 30.0	
C7D1 CFB					
n	15	34	47	81	
LS Mean (StdErr) [2]	-2.80 (1.410)	-5.25 (0.962)	-3.07 (0.992)	-7.32 (0.818)	
95% CI [2]	-5.64, 0.04	-7.19, -3.31	-5.03, -1.10	-8.94, -5.70	
Difference (95% CI) in CFB [2]		-2.45 (-5.63, 0.73)		-4.25 (-6.40, -2.11)	
Hedges'G (95% CI) in CFB		-0.43 (-1.08, 0.18)		-0.59 (-0.97, -0.23)	
p-value [3]		0.127		<0.001	
					0.377

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-pp-sex-a.sas Date: 15:34/07AUG2023

Table 35.2.2.4.4.2.3a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	32	52	35	71	
Mean (StdDev)	20.36 (5.665)	18.54 (5.761)	18.29 (5.961)	18.33 (5.407)	
Median	19.86	17.79	18.79	18.14	
Min, Max	10.7, 30.0	8.8, 30.0	8.1, 30.0	8.6, 29.8	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-pp-reg-a.sas Date: 15:35/07AUG2023

Table 35.2.2.4.4.2.3a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	32	51	35	68	
Mean (StdDev)	18.06 (6.727)	15.56 (5.616)	16.21 (6.405)	14.96 (5.957)	
Median	18.49	14.71	16.36	14.46	
Min, Max	4.8, 29.8	5.5, 27.4	4.6, 29.8	3.5, 30.0	
C2D1 CFB					
n	32	51	35	68	
LS Mean (StdErr) [2]	-2.94 (0.592)	-3.68 (0.514)	-1.60 (0.758)	-3.03 (0.579)	
95% CI [2]	-4.11, -1.76	-4.70, -2.65	-3.10, -0.09	-4.18, -1.88	
Difference (95% CI) in CFB [2]		-0.74 (-2.07, 0.59)		-1.44 (-3.09, 0.22)	
p-value [3]		0.272		0.088	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-pp-reg-a.sas Date: 15:35/07AUG2023

Table 35.2.2.4.4.2.3a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	32	50	35	67	
Mean (StdDev)	17.96 (7.313)	13.89 (6.033)	15.37 (6.659)	13.24 (6.312)	
Median	18.92	12.82	14.86	12.43	
Min, Max	5.9, 29.4	3.7, 25.4	3.7, 28.9	1.5, 30.0	
C3D1 CFB					
n	32	50	35	67	
LS Mean (StdErr) [2]	-2.51 (0.768)	-4.82 (0.668)	-2.29 (0.919)	-4.65 (0.702)	
95% CI [2]	-4.04, -0.98	-6.15, -3.49	-4.11, -0.47	-6.05, -3.26	
Difference (95% CI) in CFB [2]		-2.31 (-4.04, -0.57)		-2.36 (-4.37, -0.36)	
p-value [3]		0.010		0.021	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-pp-reg-a.sas Date: 15:35/07AUG2023

Table 35.2.2.4.4.2.3a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	30	50	34	67	
Mean (StdDev)	17.32 (7.603)	12.80 (6.497)	15.41 (6.567)	12.39 (6.668)	
Median	18.60	12.88	14.79	10.57	
Min, Max	3.8, 29.6	0.7, 24.5	4.1, 29.7	0.7, 29.9	
C4D1 CFB					
n	30	50	34	67	
LS Mean (StdErr) [2]	-3.85 (0.969)	-6.20 (0.810)	-2.03 (1.007)	-5.36 (0.764)	
95% CI [2]	-5.78, -1.92	-7.81, -4.59	-4.03, -0.03	-6.88, -3.85	
Difference (95% CI) in CFB [2]		-2.35 (-4.48, -0.21)		-3.33 (-5.52, -1.14)	
p-value [3]		0.032		0.003	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-pp-reg-a.sas Date: 15:35/07AUG2023

Table 35.2.2.4.4.2.3a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	29	51	34	68	
Mean (StdDev)	17.36 (8.373)	12.10 (6.411)	15.12 (6.253)	12.17 (6.733)	
Median	19.50	11.78	14.50	10.82	
Min, Max	1.7, 30.0	1.7, 25.2	5.5, 29.9	0.3, 30.0	
C5D1 CFB					
n	29	51	34	68	
LS Mean (StdErr) [2]	-3.99 (1.068)	-6.87 (0.857)	-2.19 (1.071)	-5.40 (0.806)	
95% CI [2]	-6.11, -1.86	-8.57, -5.16	-4.31, -0.06	-7.00, -3.80	
Difference (95% CI) in CFB [2]		-2.88 (-5.23, -0.52)		-3.21 (-5.53, -0.89)	
p-value [3]		0.017		0.007	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-pp-reg-a.sas Date: 15:35/07AUG2023

Table 35.2.2.4.4.2.3a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	28	50	34	68	
Mean (StdDev)	16.84 (8.026)	11.65 (6.485)	14.99 (6.861)	11.56 (6.921)	
Median	17.24	10.97	14.89	10.69	
Min, Max	0.5, 30.0	1.0, 25.5	1.6, 29.6	0.1, 30.0	
C6D1 CFB					
n	28	50	34	68	
LS Mean (StdErr) [2]	-4.24 (1.104)	-7.26 (0.885)	-2.37 (1.149)	-6.07 (0.859)	
95% CI [2]	-6.44, -2.03	-9.02, -5.49	-4.65, -0.09	-7.77, -4.36	
Difference (95% CI) in CFB [2]		-3.02 (-5.49, -0.56)		-3.70 (-6.19, -1.20)	
p-value [3]		0.017		0.004	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-pp-reg-a.sas Date: 15:35/07AUG2023

Table 35.2.2.4.4.2.3a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	29	49	33	66	
Mean (StdDev)	16.96 (8.255)	10.90 (6.179)	15.23 (6.340)	11.70 (6.970)	
Median	17.00	10.31	14.64	11.25	
Min, Max	0.5, 30.0	1.3, 24.1	5.9, 30.0	0.0, 30.0	
C7D1 CFB					
n	29	49	33	66	
LS Mean (StdErr) [2]	-4.12 (1.131)	-7.89 (0.932)	-1.99 (1.154)	-5.78 (0.857)	
95% CI [2]	-6.37, -1.87	-9.75, -6.04	-4.28, 0.31	-7.48, -4.08	
Difference (95% CI) in CFB [2]		-3.77 (-6.29, -1.26)		-3.79 (-6.29, -1.29)	
Hedges'G (95% CI) in CFB		-0.59 (-1.08, -0.13)		-0.55 (-0.99, -0.13)	
p-value [3]		0.004		0.003	
					0.966

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-pp-reg-a.sas Date: 15:35/07AUG2023

Table 35.2.2.4.4.2.4a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-pp-cou-a.sas Date: 15:36/07AUG2023

Table 35.2.2.4.4.2.4a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
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Table 35.2.2.4.4.2.4a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-pp-cou-a.sas Date: 15:36/07AUG2023

Table 35.2.2.4.4.2.4a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
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Table 35.2.2.4.4.2.4a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-pp-cou-a.sas Date: 15:36/07AUG2023

Table 35.2.2.4.4.2.5a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	22	37	45	86	
Mean (StdDev)	15.37 (5.439)	13.68 (3.732)	21.19 (5.118)	20.46 (4.909)	
Median	13.18	13.86	21.07	19.96	
Min, Max	8.1, 27.0	8.6, 22.8	11.1, 30.0	11.8, 30.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
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Table 35.2.2.4.4.2.5a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	22	35	45	84	
Mean (StdDev)	13.37 (6.003)	11.39 (4.762)	18.92 (6.111)	16.81 (5.455)	
Median	11.27	11.29	18.14	16.67	
Min, Max	4.6, 26.5	3.5, 21.8	4.8, 29.8	7.9, 30.0	
C2D1 CFB					
n	22	35	45	84	
LS Mean (StdErr) [2]	-2.39 (0.695)	-2.49 (0.513)	-2.44 (0.624)	-3.95 (0.503)	
95% CI [2]	-3.78, -0.99	-3.52, -1.47	-3.67, -1.20	-4.95, -2.95	
Difference (95% CI) in CFB [2]		-0.11 (-1.63, 1.41)		-1.51 (-2.95, -0.08)	
p-value [3]		0.888		0.039	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-pp-ism-a.sas Date: 15:37/07AUG2023

Table 35.2.2.4.4.2.5a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	22	35	45	82	
Mean (StdDev)	12.79 (6.647)	9.93 (4.706)	18.47 (6.521)	15.05 (6.118)	
Median	12.14	9.79	19.07	14.80	
Min, Max	3.7, 27.5	1.5, 20.7	5.9, 29.4	4.4, 30.0	
C3D1 CFB					
n	22	35	45	82	
LS Mean (StdErr) [2]	-2.77 (0.868)	-3.83 (0.641)	-2.59 (0.763)	-5.46 (0.618)	
95% CI [2]	-4.51, -1.03	-5.12, -2.55	-4.10, -1.08	-6.69, -4.24	
Difference (95% CI) in CFB [2]		-1.06 (-2.96, 0.83)		-2.87 (-4.64, -1.11)	
p-value [3]		0.265		0.002	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-pp-ism-a.sas Date: 15:37/07AUG2023

Table 35.2.2.4.4.2.5a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	20	34	44	83	
Mean (StdDev)	12.48 (6.339)	9.12 (4.598)	18.05 (6.765)	13.98 (6.755)	
Median	11.32	8.92	18.74	13.86	
Min, Max	4.1, 25.5	0.7, 20.3	3.8, 29.7	0.7, 29.9	
C4D1 CFB					
n	20	34	44	83	
LS Mean (StdErr) [2]	-2.60 (0.903)	-4.38 (0.652)	-3.28 (0.896)	-6.68 (0.712)	
95% CI [2]	-4.41, -0.78	-5.69, -3.07	-5.05, -1.50	-8.09, -5.27	
Difference (95% CI) in CFB [2]		-1.79 (-3.77, 0.20)		-3.40 (-5.44, -1.36)	
p-value [3]		0.077		0.001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-pp-ism-a.sas Date: 15:37/07AUG2023

Table 35.2.2.4.4.2.5a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	36	44	83	
Mean (StdDev)	12.62 (6.607)	8.87 (4.589)	17.68 (7.162)	13.56 (6.811)	
Median	13.07	9.14	18.54	13.15	
Min, Max	2.3, 23.6	0.5, 19.0	1.7, 30.0	0.3, 30.0	
C5D1 CFB					
n	19	36	44	83	
LS Mean (StdErr) [2]	-2.59 (1.011)	-4.74 (0.697)	-3.67 (0.960)	-7.13 (0.763)	
95% CI [2]	-4.62, -0.57	-6.14, -3.34	-5.57, -1.77	-8.64, -5.62	
Difference (95% CI) in CFB [2]		-2.14 (-4.36, 0.08)		-3.46 (-5.65, -1.27)	
p-value [3]		0.058		0.002	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-pp-ism-a.sas Date: 15:37/07AUG2023

Table 35.2.2.4.4.2.5a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	20	37	42	81	
Mean (StdDev)	12.74 (5.980)	8.37 (4.351)	17.29 (7.627)	13.07 (7.096)	
Median	13.35	9.46	17.59	12.86	
Min, Max	1.6, 22.9	0.1, 17.9	0.5, 30.0	0.7, 30.0	
C6D1 CFB					
n	20	37	42	81	
LS Mean (StdErr) [2]	-2.53 (1.036)	-5.29 (0.722)	-3.98 (1.041)	-7.70 (0.819)	
95% CI [2]	-4.61, -0.45	-6.74, -3.84	-6.05, -1.92	-9.32, -6.08	
Difference (95% CI) in CFB [2]		-2.76 (-5.02, -0.50)		-3.72 (-6.10, -1.33)	
p-value [3]		0.018		0.002	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-pp-ism-a.sas Date: 15:37/07AUG2023

Table 35.2.2.4.4.2.5a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	19	36	43	79	
Mean (StdDev)	12.97 (5.496)	8.38 (4.335)	17.39 (7.621)	12.71 (7.058)	
Median	12.86	7.97	18.22	12.33	
Min, Max	5.9, 23.0	0.7, 19.1	0.5, 30.0	0.0, 30.0	
C7D1 CFB					
n	19	36	43	79	
LS Mean (StdErr) [2]	-2.48 (1.062)	-5.30 (0.732)	-3.82 (1.034)	-7.90 (0.835)	
95% CI [2]	-4.61, -0.35	-6.77, -3.83	-5.86, -1.77	-9.55, -6.25	
Difference (95% CI) in CFB [2]		-2.82 (-5.15, -0.49)		-4.08 (-6.45, -1.71)	
Hedges'G (95% CI) in CFB		-0.62 (-1.23, -0.07)		-0.56 (-0.96, -0.19)	
p-value [3]		0.019		<0.001	
					0.531

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-pp-ism-a.sas Date: 15:37/07AUG2023

Table 35.2.2.4.4.2.7a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	63	114	4	9	
Mean (StdDev)	19.51 (5.758)	18.22 (5.521)	15.57 (7.324)	20.91 (5.427)	
Median	19.69	18.00	14.39	21.29	
Min, Max	8.5, 30.0	8.6, 30.0	8.1, 25.4	13.9, 29.6	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
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Table 35.2.2.4.4.2.7a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	63	110	4	9	
Mean (StdDev)	17.26 (6.668)	15.03 (5.657)	14.55 (4.875)	17.43 (7.329)	
Median	16.79	14.46	13.89	15.08	
Min, Max	4.6, 29.8	3.5, 28.1	9.9, 20.6	4.9, 30.0	
C2D1 CFB					
n	63	110	4	9	
LS Mean (StdErr) [2]	-2.30 (0.493)	-3.31 (0.399)	1.62 (3.849)	-1.23 (3.050)	
95% CI [2]	-3.27, -1.33	-4.10, -2.53	-7.08, 10.33	-8.13, 5.66	
Difference (95% CI) in CFB [2]		-1.02 (-2.11, 0.08)		-2.86 (-10.37, 4.65)	
p-value [3]		0.068		0.412	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
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Table 35.2.2.4.4.2.7a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	63	108	4	9	
Mean (StdDev)	16.80 (7.179)	13.30 (5.932)	13.61 (3.775)	16.14 (8.609)	
Median	16.58	12.29	14.57	16.29	
Min, Max	3.7, 29.4	2.6, 27.1	8.6, 16.7	1.5, 30.0	
C3D1 CFB					
n	63	108	4	9	
LS Mean (StdErr) [2]	-2.43 (0.606)	-4.77 (0.491)	1.72 (4.643)	-1.78 (3.679)	
95% CI [2]	-3.63, -1.23	-5.74, -3.80	-8.78, 12.23	-10.10, 6.55	
Difference (95% CI) in CFB [2]		-2.34 (-3.69, -0.99)		-3.50 (-12.56, 5.56)	
p-value [3]		<0.001		0.405	

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Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
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Table 35.2.2.4.4.2.7a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	60	108	4	9	
Mean (StdDev)	16.46 (7.250)	12.39 (6.278)	14.00 (3.348)	14.65 (9.676)	
Median	17.39	11.46	13.11	12.36	
Min, Max	3.8, 29.7	0.7, 26.6	11.0, 18.8	0.7, 29.9	
C4D1 CFB					
n	60	108	4	9	
LS Mean (StdErr) [2]	-2.93 (0.699)	-5.71 (0.553)	3.00 (5.512)	-2.50 (4.368)	
95% CI [2]	-4.31, -1.55	-6.80, -4.62	-9.47, 15.47	-12.38, 7.38	
Difference (95% CI) in CFB [2]		-2.78 (-4.31, -1.24)		-5.50 (-16.26, 5.26)	
p-value [3]		<0.001		0.277	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
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Table 35.2.2.4.4.2.7a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	59	110	4	9	
Mean (StdDev)	16.46 (7.416)	11.75 (6.075)	11.65 (4.308)	16.99 (10.257)	
Median	17.14	10.89	12.79	22.71	
Min, Max	1.7, 30.0	0.3, 25.2	5.5, 15.5	0.5, 30.0	
C5D1 CFB					
n	59	110	4	9	
LS Mean (StdErr) [2]	-2.96 (0.735)	-6.28 (0.567)	2.60 (6.365)	1.38 (5.044)	
95% CI [2]	-4.42, -1.51	-7.40, -5.16	-11.80, 17.00	-10.03, 12.79	
Difference (95% CI) in CFB [2]		-3.32 (-4.93, -1.71)		-1.22 (-13.64, 11.20)	
p-value [3]		<0.0001		0.829	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
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Table 35.2.2.4.4.2.7a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	58	109	4	9	
Mean (StdDev)	16.07 (7.581)	11.28 (6.322)	12.27 (2.226)	15.44 (10.055)	
Median	17.10	10.64	13.04	12.00	
Min, Max	0.5, 30.0	0.7, 29.6	9.0, 14.0	0.1, 30.0	
C6D1 CFB					
n	58	109	4	9	
LS Mean (StdErr) [2]	-3.21 (0.805)	-6.75 (0.620)	3.11 (5.415)	-0.04 (4.291)	
95% CI [2]	-4.80, -1.63	-7.98, -5.53	-9.14, 15.36	-9.75, 9.66	
Difference (95% CI) in CFB [2]		-3.54 (-5.31, -1.76)		-3.16 (-13.72, 7.41)	
p-value [3]		<0.001		0.516	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
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Table 35.2.2.4.4.2.7a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	59	106	3	9	
Mean (StdDev)	16.15 (7.438)	11.04 (6.258)	13.81 (2.837)	15.07 (9.752)	
Median	16.58	10.48	12.86	11.93	
Min, Max	0.5, 30.0	0.0, 29.0	11.6, 17.0	0.7, 30.0	
C7D1 CFB					
n	59	106	3	9	
LS Mean (StdErr) [2]	-3.04 (0.802)	-6.84 (0.629)	3.67 (6.545)	-0.58 (4.762)	
95% CI [2]	-4.63, -1.46	-8.08, -5.60	-11.43, 18.76	-11.56, 10.40	
Difference (95% CI) in CFB [2]		-3.80 (-5.57, -2.02)		-4.24 (-16.92, 8.44)	
Hedges'G (95% CI) in CFB		-0.59 (-0.93, -0.27)		-0.28 (-1.85, 1.14)	
p-value [3]		<0.0001		0.463	
					0.829

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-pp-ecog-a.sas Date: 15:38/07AUG2023

Table 35.2.2.4.4.2.8a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	64	113	
Mean (StdDev)	22.24 (4.299)	21.37 (6.779)	19.14 (5.923)	18.16 (5.372)	
Median	21.07	21.68	18.93	18.00	
Min, Max	18.6, 27.0	8.8, 29.6	8.1, 30.0	8.6, 30.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-pp-thpy-a.sas Date: 15:39/07AUG2023

Table 35.2.2.4.4.2.8a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	64	109	
Mean (StdDev)	19.71 (7.423)	18.19 (5.754)	16.97 (6.575)	14.94 (5.750)	
Median	20.86	17.52	16.68	14.42	
Min, Max	11.8, 26.5	8.0, 25.9	4.6, 29.8	3.5, 30.0	
C2D1 CFB					
n	3	10	64	109	
LS Mean (StdErr) [2]	-2.28 (2.568)	-2.48 (2.272)	-2.18 (0.509)	-3.31 (0.413)	
95% CI [2]	-8.09, 3.53	-7.62, 2.66	-3.18, -1.17	-4.12, -2.49	
Difference (95% CI) in CFB [2]		-0.21 (-6.85, 6.43)		-1.13 (-2.25, -0.01)	
p-value [3]		0.946		0.048	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-pp-thpy-a.sas Date: 15:39/07AUG2023

Table 35.2.2.4.4.2.8a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	8	64	109	
Mean (StdDev)	18.88 (3.857)	16.64 (6.134)	16.50 (7.161)	13.29 (6.145)	
Median	21.00	16.45	16.37	12.29	
Min, Max	14.4, 21.2	8.5, 25.0	3.7, 29.4	1.5, 30.0	
C3D1 CFB					
n	3	8	64	109	
LS Mean (StdErr) [2]	-2.59 (4.215)	-4.52 (3.722)	-2.35 (0.611)	-4.68 (0.496)	
95% CI [2]	-12.55, 7.38	-13.32, 4.28	-3.56, -1.15	-5.66, -3.70	
Difference (95% CI) in CFB [2]		-1.93 (-13.39, 9.52)		-2.33 (-3.67, -0.98)	
p-value [3]		0.702		<0.001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-pp-thpy-a.sas Date: 15:39/07AUG2023

Table 35.2.2.4.4.2.8a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	3	9	61	108	
Mean (StdDev)	17.29 (7.631)	14.05 (6.532)	16.26 (7.116)	12.44 (6.589)	
Median	21.23	12.79	16.15	11.46	
Min, Max	8.5, 22.2	6.6, 24.6	3.8, 29.7	0.7, 29.9	
C4D1 CFB					
n	3	9	61	108	
LS Mean (StdErr) [2]	-4.60 (4.373)	-7.06 (3.865)	-2.65 (0.710)	-5.49 (0.564)	
95% CI [2]	-14.69, 5.48	-15.97, 1.85	-4.05, -1.25	-6.60, -4.38	
Difference (95% CI) in CFB [2]		-2.46 (-14.01, 9.09)		-2.84 (-4.38, -1.29)	
p-value [3]		0.637		<0.001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-pp-thpy-a.sas Date: 15:39/07AUG2023

Table 35.2.2.4.4.2.8a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	9	60	110	
Mean (StdDev)	16.98 (8.735)	12.55 (6.631)	16.11 (7.338)	12.11 (6.594)	
Median	21.23	10.36	16.04	11.74	
Min, Max	6.9, 22.8	6.8, 24.5	1.7, 30.0	0.3, 30.0	
C5D1 CFB					
n	3	9	60	110	
LS Mean (StdErr) [2]	-5.33 (4.196)	-9.21 (3.709)	-2.80 (0.766)	-5.72 (0.594)	
95% CI [2]	-15.00, 4.35	-17.76, -0.66	-4.31, -1.29	-6.89, -4.55	
Difference (95% CI) in CFB [2]		-3.88 (-14.97, 7.20)		-2.92 (-4.59, -1.26)	
p-value [3]		0.443		<0.001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-pp-thpy-a.sas Date: 15:39/07AUG2023

Table 35.2.2.4.4.2.8a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	59	109	
Mean (StdDev)	15.80 (8.304)	11.63 (6.173)	15.83 (7.436)	11.59 (6.781)	
Median	20.50	10.36	15.86	11.00	
Min, Max	6.2, 20.7	5.8, 23.4	0.5, 30.0	0.1, 30.0	
C6D1 CFB					
n	3	9	59	109	
LS Mean (StdErr) [2]	-6.49 (4.295)	-10.12 (3.796)	-2.93 (0.812)	-6.23 (0.628)	
95% CI [2]	-16.40, 3.41	-18.88, -1.37	-4.53, -1.32	-7.47, -4.99	
Difference (95% CI) in CFB [2]		-3.63 (-14.98, 7.72)		-3.30 (-5.08, -1.52)	
p-value [3]		0.482		<0.001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
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Table 35.2.2.4.4.2.8a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	9	59	106	
Mean (StdDev)	16.37 (8.183)	12.70 (6.237)	16.02 (7.318)	11.24 (6.676)	
Median	20.71	10.31	16.56	10.62	
Min, Max	6.9, 21.5	5.2, 24.7	0.5, 30.0	0.0, 30.0	
C7D1 CFB					
n	3	9	59	106	
LS Mean (StdErr) [2]	-5.73 (4.740)	-8.65 (4.189)	-2.72 (0.818)	-6.42 (0.638)	
95% CI [2]	-16.66, 5.20	-18.31, 1.01	-4.34, -1.11	-7.68, -5.16	
Difference (95% CI) in CFB [2]		-2.91 (-15.44, 9.61)		-3.69 (-5.48, -1.90)	
Hedges'G (95% CI) in CFB		-0.23 (-1.78, 1.20)		-0.57 (-0.90, -0.25)	
p-value [3]		0.606		<0.0001	
					0.860

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-pp-thpy-a.sas Date: 15:39/07AUG2023

Table 35.2.1.3.2.2a
Proportion of Patients with >=50% Reduction in TSS of ISM-SAF at C7D1
Per-Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >=50% Reduction in TSS at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Overall	5/ 67 (7.5) (2.5, 16.6)	34/123 (27.6) (20.0, 36.4)	4.53 (1.72, 16.75) <0.001	3.67 (1.52, 8.82) 0.004	0.21 (0.10, 0.31) <0.001	
Age Group (Years)						0.976
< 65	5/ 56 (8.9) (3.0, 19.6)	30/117 (25.6) (18.0, 34.5)	3.43 (1.23, 12.27) 0.011	2.89 (1.17, 7.16) 0.022	0.17 (0.06, 0.28) 0.003	
>= 65	0/ 11 (0.0) (0.0, 28.5)	4/ 6 (66.7) (22.3, 95.7)	NE (1.54, NE) 0.011	NE (NE, NE) NE	0.73 (0.40, 1.00) <0.0001	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of TSS prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to C7D1 visit, the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.
Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tss-resp2-pp-a.sas Date: 18:00/13APR2023

Table 35.2.1.3.2.2a
Proportion of Patients with >=50% Reduction in TSS of ISM-SAF at C7D1
Per-Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >=50% Reduction in TSS at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Sex						0.883
Male	1/ 15 (6.7) (0.2, 31.9)	8/ 35 (22.9) (10.4, 40.1)	4.24 (0.46, 196.66) 0.179	3.43 (0.47, 24.79) 0.222	0.16 (-0.03, 0.35) 0.091	
Female	4/ 52 (7.7) (2.1, 18.5)	26/ 88 (29.5) (20.3, 40.2)	4.75 (1.61, 21.87) 0.002	3.80 (1.43, 10.07) 0.007	0.23 (0.10, 0.35) <0.001	
Region						0.176
North America	4/ 32 (12.5) (3.5, 29.0)	14/ 52 (26.9) (15.6, 41.0)	2.38 (0.64, 11.17) 0.152	2.04 (0.74, 5.61) 0.167	0.14 (-0.04, 0.32) 0.126	
Europe	1/ 35 (2.9) (0.1, 14.9)	20/ 71 (28.2) (18.1, 40.1)	13.94 (2.08, 634.32) 0.001	10.09 (1.44, 70.63) 0.020	0.26 (0.14, 0.38) <0.0001	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of TSS prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to C7D1 visit, the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.
Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.1.3.2.2a
Proportion of Patients with >=50% Reduction in TSS of ISM-SAF at C7D1
Per-Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >=50% Reduction in TSS at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country						>0.999
BEL	0/ 1 (0.0) (0.0, 97.5)	0/ 2 (0.0) (0.0, 84.2)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
CAN	0/ 5 (0.0) (0.0, 52.2)	3/ 8 (37.5) (8.5, 75.5)	NE (0.28, NE) 0.109	NE (NE, NE) NE	0.44 (0.06, 0.82) 0.021	
CHE	0/ 1 (0.0) (0.0, 97.5)	1/ 2 (50.0) (1.3, 98.7)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
DEU	1/ 14 (7.1) (0.2, 33.9)	4/ 17 (23.5) (6.8, 49.9)	3.63 (0.31, 221.25) 0.225	3.10 (0.42, 22.74) 0.266	0.17 (-0.09, 0.42) 0.205	
DNK	0/0	1/ 1 (100.0) (2.5, 100.0)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of TSS prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to C7D1 visit, the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.
Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.1.3.2.2a
Proportion of Patients with >=50% Reduction in TSS of ISM-SAF at C7D1
Per-Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >=50% Reduction in TSS at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
ESP	0/ 3 (0.0) (0.0, 70.8)	6/ 13 (46.2) (19.2, 74.9)	NE (0.46, NE) 0.112	NE (NE, NE) NE	0.56 (0.26, 0.87) <0.001	
FRA	0/ 5 (0.0) (0.0, 52.2)	2/ 10 (20.0) (2.5, 55.6)	NE (0.08, NE) 0.378	NE (NE, NE) NE	0.17 (-0.10, 0.43) 0.221	
GBR	0/ 5 (0.0) (0.0, 52.2)	2/ 10 (20.0) (2.5, 55.6)	NE (0.15, NE) 0.292	NE (NE, NE) NE	0.23 (-0.07, 0.54) 0.133	
ITA	0/0	0/ 3 (0.0) (0.0, 70.8)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of TSS prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to C7D1 visit, the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.
Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.1.3.2.2a
Proportion of Patients with >=50% Reduction in TSS of ISM-SAF at C7D1
Per-Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >=50% Reduction in TSS at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
NLD	0/ 3 (0.0) (0.0, 70.8)	2/ 7 (28.6) (3.7, 71.0)	NE (0.05, NE) 0.317	NE (NE, NE) NE	0.33 (-0.20, 0.87) 0.221	
NOR	0/ 2 (0.0) (0.0, 84.2)	1/ 5 (20.0) (0.5, 71.6)	NE (0.02, NE) 0.564	NE (NE, NE) NE	0.18 (-0.17, 0.52) 0.313	
SWE	0/ 1 (0.0) (0.0, 97.5)	1/ 1 (100.0) (2.5, 100.0)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
USA	4/ 27 (14.8) (4.2, 33.7)	11/ 44 (25.0) (13.2, 40.3)	1.99 (0.49, 9.48) 0.300	1.73 (0.61, 4.89) 0.304	0.11 (-0.08, 0.30) 0.264	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of TSS prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to C7D1 visit, the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.
Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.1.3.2.2a
Proportion of Patients with >=50% Reduction in TSS of ISM-SAF at C7D1
Per-Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >=50% Reduction in TSS at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Baseline ISM Status						0.968
Moderate	0/ 22 (0.0) (0.0, 15.4)	13/ 37 (35.1) (20.2, 52.5)	NE (3.51, NE) 0.001	NE (NE, NE) NE	0.38 (0.22, 0.54) <0.0001	
Severe	5/ 45 (11.1) (3.7, 24.1)	21/ 86 (24.4) (15.8, 34.9)	2.51 (0.82, 9.13) 0.083	2.14 (0.86, 5.32) 0.102	0.13 (-0.00, 0.26) 0.053	
Baseline Serum Tryptase (ng/mL)						0.434
< 20	1/ 13 (7.7) (0.2, 36.0)	4/ 26 (15.4) (4.4, 34.9)	2.07 (0.16, 110.20) 0.563	1.94 (0.20, 19.11) 0.571	0.07 (-0.13, 0.27) 0.511	
>= 20	4/ 54 (7.4) (2.1, 17.9)	30/ 97 (30.9) (21.9, 41.1)	5.18 (1.81, 23.39) <0.001	4.05 (1.55, 10.55) 0.004	0.24 (0.12, 0.36) <0.0001	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of TSS prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to C7D1 visit, the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.
Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.1.3.2.2a
Proportion of Patients with >=50% Reduction in TSS of ISM-SAF at C7D1
Per-Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >=50% Reduction in TSS at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
ECOG Status						0.982
0 or 1	5/ 63 (7.9) (2.6, 17.6)	32/114 (28.1) (20.1, 37.3)	4.36 (1.61, 15.90) 0.002	3.50 (1.45, 8.48) 0.005	0.20 (0.09, 0.31) <0.001	
2+	0/ 4 (0.0) (0.0, 60.2)	2/ 9 (22.2) (2.8, 60.0)	NE (0.17, NE) 0.257	NE (NE, NE) NE	0.30 (-0.02, 0.62) 0.068	
Prior TKI therapy						0.976
Yes	0/ 3 (0.0) (0.0, 70.8)	2/ 10 (20.0) (2.5, 55.6)	NE (0.08, NE) 0.426	NE (NE, NE) NE	0.22 (-0.08, 0.53) 0.151	
No	5/ 64 (7.8) (2.6, 17.3)	32/113 (28.3) (20.2, 37.6)	4.46 (1.68, 16.71) 0.001	3.61 (1.49, 8.77) 0.005	0.21 (0.10, 0.32) <0.001	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of TSS prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to C7D1 visit, the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.
Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

Table 35.2.1.3.1.2a
Summary of Patients with >=30% Reduction in ISM-SAF TSS at C7D1
Per-Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >=30% Reduction in TSS at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Overall	19/ 67 (28.4) (18.0, 40.7)	59/123 (48.0) (38.9, 57.2)	2.28 (1.16, 4.61) 0.011	1.67 (1.10, 2.55) 0.017	0.19 (0.05, 0.34) 0.008	
Age Group (Years)						0.962
< 65	18/ 56 (32.1) (20.3, 46.0)	53/117 (45.3) (36.1, 54.8)	1.76 (0.86, 3.66) 0.098	1.42 (0.92, 2.19) 0.113	0.13 (-0.02, 0.29) 0.086	
>= 65	1/ 11 (9.1) (0.2, 41.3)	6/ 6 (100.0) (54.1, 100.0)	NE (2.95, NE) 0.002	22.00 (0.51, 945.61) 0.107	0.95 (0.87, 1.00) <0.0001	

Abbreviations: TSS = total symptom score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of TSS prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to C7D1 visit, the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

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Table 35.2.1.3.1.2a
Summary of Patients with >=30% Reduction in ISM-SAF TSS at C7D1
Per-Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >=30% Reduction in TSS at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Sex						0.126
Male	6/ 15 (40.0) (16.3, 67.7)	14/ 35 (40.0) (23.9, 57.9)	0.95 (0.24, 3.98) 0.939	0.97 (0.48, 1.98) >0.999	-0.01 (-0.31, 0.28) 0.937	
Female	13/ 52 (25.0) (14.0, 38.9)	45/ 88 (51.1) (40.2, 61.9)	3.11 (1.39, 7.28) 0.003	2.06 (1.23, 3.46) 0.006	0.27 (0.10, 0.43) 0.001	
Region						0.819
North America	9/ 32 (28.1) (13.7, 46.7)	26/ 52 (50.0) (35.8, 64.2)	2.40 (0.81, 7.19) 0.083	1.68 (0.91, 3.11) 0.097	0.20 (-0.01, 0.41) 0.068	
Europe	10/ 35 (28.6) (14.6, 46.3)	33/ 71 (46.5) (34.5, 58.7)	2.31 (0.89, 6.13) 0.062	1.67 (0.94, 2.96) 0.080	0.19 (0.00, 0.38) 0.047	

Abbreviations: TSS = total symptom score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of TSS prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to C7D1 visit, the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

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Table 35.2.1.3.1.2a
Summary of Patients with >=30% Reduction in ISM-SAF TSS at C7D1
Per-Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >=30% Reduction in TSS at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country						0.993
BEL	1/ 1 (100.0) (2.5, 100.0)	0/ 2 (0.0) (0.0, 84.2)	0.00 (0.00, 19.00) 0.317	0.00 (NE, NE) NE	-1.00 (-1.00, -1.00) NE	
CAN	1/ 5 (20.0) (0.5, 71.6)	6/ 8 (75.0) (34.9, 96.8)	NE (0.52, NE) 0.059	3.50 (0.69, 17.84) 0.132	0.60 (0.20, 1.00) 0.004	
CHE	0/ 1 (0.0) (0.0, 97.5)	1/ 2 (50.0) (1.3, 98.7)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
DEU	4/ 14 (28.6) (8.4, 58.1)	7/ 17 (41.2) (18.4, 67.1)	1.86 (0.33, 11.24) 0.422	1.50 (0.56, 4.01) 0.419	0.14 (-0.20, 0.49) 0.406	
DNK	0/0	1/ 1 (100.0) (2.5, 100.0)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	

Abbreviations: TSS = total symptom score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of TSS prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to C7D1 visit, the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

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Table 35.2.1.3.1.2a
Summary of Patients with >=30% Reduction in ISM-SAF TSS at C7D1
Per-Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >=30% Reduction in TSS at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
ESP	1/ 3 (33.3) (0.8, 90.6)	8/ 13 (61.5) (31.6, 86.1)	4.00 (0.16, 255.34) 0.273	2.20 (0.35, 13.99) 0.404	0.38 (-0.26, 1.00) 0.246	
FRA	1/ 5 (20.0) (0.5, 71.6)	5/ 10 (50.0) (18.7, 81.3)	3.00 (0.24, 183.56) 0.299	3.00 (0.24, 37.67) 0.395	0.33 (-0.25, 0.91) 0.261	
GBR	1/ 5 (20.0) (0.5, 71.6)	5/ 10 (50.0) (18.7, 81.3)	5.63 (0.24, 326.75) 0.252	2.85 (0.42, 19.39) 0.284	0.35 (-0.12, 0.82) 0.150	
ITA	0/0	0/ 3 (0.0) (0.0, 70.8)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	

Abbreviations: TSS = total symptom score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of TSS prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to C7D1 visit, the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

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Table 35.2.1.3.1.2a
Summary of Patients with >=30% Reduction in ISM-SAF TSS at C7D1
Per-Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >=30% Reduction in TSS at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
NLD	1/ 3 (33.3) (0.8, 90.6)	3/ 7 (42.9) (9.9, 81.6)	1.00 (0.01, 117.33) >0.999	1.00 (0.10, 9.61) >0.999	0.00 (-0.75, 0.75) >0.999	
NOR	1/ 2 (50.0) (1.3, 98.7)	2/ 5 (40.0) (5.3, 85.3)	0.75 (0.01, 58.83) 0.808	0.75 (0.05, 10.34) >0.999	-0.12 (-1.00, 0.94) 0.827	
SWE	0/ 1 (0.0) (0.0, 97.5)	1/ 1 (100.0) (2.5, 100.0)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
USA	8/ 27 (29.6) (13.8, 50.2)	20/ 44 (45.5) (30.4, 61.2)	1.83 (0.57, 5.77) 0.269	1.45 (0.74, 2.84) 0.276	0.14 (-0.09, 0.37) 0.247	

Abbreviations: TSS = total symptom score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of TSS prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to C7D1 visit, the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

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Table 35.2.1.3.1.2a
Summary of Patients with >=30% Reduction in ISM-SAF TSS at C7D1
Per-Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >=30% Reduction in TSS at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Baseline ISM Status						0.370
Moderate	4/ 22 (18.2) (5.2, 40.3)	17/ 37 (45.9) (29.5, 63.1)	3.61 (0.93, 18.24) 0.038	2.42 (0.97, 6.04) 0.057	0.28 (0.04, 0.52) 0.024	
Severe	15/ 45 (33.3) (20.0, 49.0)	42/ 86 (48.8) (37.9, 59.9)	1.91 (0.85, 4.37) 0.090	1.47 (0.92, 2.37) 0.109	0.16 (-0.02, 0.33) 0.078	
Baseline Serum Tryptase (ng/mL)						0.126
< 20	6/ 13 (46.2) (19.2, 74.9)	11/ 26 (42.3) (23.4, 63.1)	0.87 (0.18, 4.29) 0.848	0.93 (0.44, 1.96) >0.999	-0.03 (-0.37, 0.31) 0.845	
>= 20	13/ 54 (24.1) (13.5, 37.6)	48/ 97 (49.5) (39.2, 59.8)	3.00 (1.36, 6.84) 0.003	2.01 (1.21, 3.33) 0.007	0.25 (0.10, 0.40) 0.001	

Abbreviations: TSS = total symptom score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of TSS prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to C7D1 visit, the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

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Table 35.2.1.3.1.2a
Summary of Patients with >=30% Reduction in ISM-SAF TSS at C7D1
Per-Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >=30% Reduction in TSS at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
ECOG Status						0.681
0 or 1	18/ 63 (28.6) (17.9, 41.3)	56/114 (49.1) (39.6, 58.7)	2.40 (1.18, 4.95) 0.009	1.71 (1.11, 2.64) 0.015	0.21 (0.06, 0.35) 0.006	
2+	1/ 4 (25.0) (0.6, 80.6)	3/ 9 (33.3) (7.5, 70.1)	1.50 (0.06, 98.22) 0.757	1.33 (0.24, 7.28) 0.740	0.10 (-0.51, 0.71) 0.748	
Prior TKI therapy						0.868
Yes	1/ 3 (33.3) (0.8, 90.6)	6/ 10 (60.0) (26.2, 87.8)	NE (0.05, NE) 0.317	1.75 (0.40, 7.61) 0.456	0.24 (-0.16, 0.65) 0.241	
No	18/ 64 (28.1) (17.6, 40.8)	53/113 (46.9) (37.5, 56.5)	2.20 (1.09, 4.55) 0.018	1.65 (1.06, 2.55) 0.025	0.19 (0.04, 0.33) 0.013	

Abbreviations: TSS = total symptom score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of TSS prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to C7D1 visit, the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

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Table 35.2.1.3.3.2a
Proportion of Patients with >=16.5 Points Reduction in TSS of ISM-SAF at C7D1
Per-Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >=16.5 Point Reduction in TSS at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Overall	19/ 67 (28.4) (18.0, 40.7)	54/123 (43.9) (35.0, 53.1)	1.88 (0.96, 3.99) 0.047	1.50 (0.98, 2.31) 0.065	0.14 (0.00, 0.29) 0.045	
Age Group (Years)						0.967
< 65	19/ 56 (33.9) (21.8, 47.8)	49/117 (41.9) (32.8, 51.4)	1.44 (0.71, 3.08) 0.275	1.26 (0.82, 1.94) 0.300	0.09 (-0.07, 0.24) 0.273	
>= 65	0/ 11 (0.0) (0.0, 28.5)	5/ 6 (83.3) (35.9, 99.6)	NE (2.27, NE) 0.003	NE (NE, NE) NE	0.86 (0.62, 1.00) <0.0001	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of TSS prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to C7D1 visit, the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.
Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.1.3.3.2a
Proportion of Patients with >=16.5 Points Reduction in TSS of ISM-SAF at C7D1
Per-Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >=16.5 Point Reduction in TSS at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Sex						0.063
Male	6/ 15 (40.0) (16.3, 67.7)	11/ 35 (31.4) (16.9, 49.3)	0.63 (0.14, 2.76) 0.456	0.74 (0.33, 1.63) >0.999	-0.11 (-0.40, 0.19) 0.472	
Female	13/ 52 (25.0) (14.0, 38.9)	43/ 88 (48.9) (38.1, 59.8)	2.84 (1.27, 6.95) 0.006	1.93 (1.15, 3.23) 0.013	0.23 (0.08, 0.39) 0.004	
Region						0.650
North America	10/ 32 (31.3) (16.1, 50.0)	23/ 52 (44.2) (30.5, 58.7)	1.51 (0.53, 4.66) 0.385	1.30 (0.70, 2.40) 0.406	0.10 (-0.12, 0.31) 0.389	
Europe	9/ 35 (25.7) (12.5, 43.3)	31/ 71 (43.7) (31.9, 56.0)	2.34 (0.89, 6.81) 0.059	1.72 (0.93, 3.16) 0.084	0.19 (0.00, 0.37) 0.048	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of TSS prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to C7D1 visit, the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.
Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.1.3.3.2a
Proportion of Patients with >=16.5 Points Reduction in TSS of ISM-SAF at C7D1
Per-Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >=16.5 Point Reduction in TSS at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country						>0.999
BEL	1/ 1 (100.0) (2.5, 100.0)	0/ 2 (0.0) (0.0, 84.2)	0.00 (0.00, 19.00) 0.317	0.00 (NE, NE) NE	-1.00 (-1.00, -1.00) NE	
CAN	1/ 5 (20.0) (0.5, 71.6)	4/ 8 (50.0) (15.7, 84.3)	2.17 (0.11, 176.61) 0.473	2.17 (0.23, 20.60) 0.501	0.28 (-0.49, 1.00) 0.474	
CHE	0/ 1 (0.0) (0.0, 97.5)	1/ 2 (50.0) (1.3, 98.7)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
DEU	5/ 14 (35.7) (12.8, 64.9)	9/ 17 (52.9) (27.8, 77.0)	2.36 (0.42, 14.69) 0.268	1.59 (0.68, 3.70) 0.284	0.20 (-0.14, 0.54) 0.246	
DNK	0/0	1/ 1 (100.0) (2.5, 100.0)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of TSS prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to C7D1 visit, the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.
Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.1.3.3.2a
Proportion of Patients with >=16.5 Points Reduction in TSS of ISM-SAF at C7D1
Per-Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >=16.5 Point Reduction in TSS at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
ESP	0/ 3 (0.0) (0.0, 70.8)	8/ 13 (61.5) (31.6, 86.1)	NE (0.81, NE) 0.036	NE (NE, NE) NE	0.63 (0.29, 0.96) <0.001	
FRA	0/ 5 (0.0) (0.0, 52.2)	4/ 10 (40.0) (12.2, 73.8)	NE (0.31, NE) 0.127	NE (NE, NE) NE	0.33 (-0.02, 0.69) 0.064	
GBR	1/ 5 (20.0) (0.5, 71.6)	4/ 10 (40.0) (12.2, 73.8)	2.75 (0.13, 170.00) 0.499	2.05 (0.26, 16.25) 0.497	0.20 (-0.29, 0.68) 0.425	
ITA	0/0	0/ 3 (0.0) (0.0, 70.8)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of TSS prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to C7D1 visit, the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.
Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.1.3.3.2a
Proportion of Patients with >=16.5 Points Reduction in TSS of ISM-SAF at C7D1
Per-Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >=16.5 Point Reduction in TSS at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
NLD	0/ 3 (0.0) (0.0, 70.8)	3/ 7 (42.9) (9.9, 81.6)	NE (0.05, NE) 0.317	NE (NE, NE) NE	0.33 (-0.20, 0.87) 0.221	
NOR	1/ 2 (50.0) (1.3, 98.7)	0/ 5 (0.0) (0.0, 52.2)	0.00 (0.00, 9.50) 0.157	0.00 (NE, NE) NE	-0.47 (-1.00, 0.24) 0.195	
SWE	1/ 1 (100.0) (2.5, 100.0)	1/ 1 (100.0) (2.5, 100.0)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
USA	9/ 27 (33.3) (16.5, 54.0)	19/ 44 (43.2) (28.3, 59.0)	1.45 (0.46, 4.83) 0.482	1.25 (0.66, 2.37) 0.492	0.08 (-0.15, 0.32) 0.477	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of TSS prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to C7D1 visit, the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.
Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.1.3.3.2a
Proportion of Patients with >=16.5 Points Reduction in TSS of ISM-SAF at C7D1
Per-Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >=16.5 Point Reduction in TSS at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Baseline ISM Status						0.098
Moderate	1/ 22 (4.5) (0.1, 22.8)	12/ 37 (32.4) (18.0, 49.8)	6.99 (1.12, 418.46) 0.019	5.20 (1.01, 26.61) 0.048	0.27 (0.07, 0.46) 0.007	
Severe	18/ 45 (40.0) (25.7, 55.7)	42/ 86 (48.8) (37.9, 59.9)	1.41 (0.65, 3.21) 0.328	1.23 (0.79, 1.93) 0.360	0.09 (-0.09, 0.27) 0.334	
Baseline Serum Tryptase (ng/mL)						0.001
< 20	9/ 13 (69.2) (38.6, 90.9)	8/ 26 (30.8) (14.3, 51.8)	0.21 (0.04, 1.13) 0.036	0.46 (0.22, 0.94) >0.999	-0.37 (-0.69, -0.05) 0.023	
>= 20	10/ 54 (18.5) (9.3, 31.4)	46/ 97 (47.4) (37.2, 57.8)	3.90 (1.61, 9.65) <0.001	2.37 (1.34, 4.17) 0.003	0.27 (0.13, 0.41) <0.001	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of TSS prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to C7D1 visit, the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.
Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.1.3.3.2a
Proportion of Patients with >=16.5 Points Reduction in TSS of ISM-SAF at C7D1
Per-Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >=16.5 Point Reduction in TSS at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
ECOG Status						0.939
0 or 1	18/ 63 (28.6) (17.9, 41.3)	50/114 (43.9) (34.6, 53.5)	1.90 (0.95, 4.15) 0.051	1.51 (0.97, 2.36) 0.070	0.15 (0.00, 0.29) 0.048	
2+	1/ 4 (25.0) (0.6, 80.6)	4/ 9 (44.4) (13.7, 78.8)	2.33 (0.10, 143.99) 0.544	1.67 (0.34, 8.26) 0.532	0.20 (-0.39, 0.79) 0.510	
Prior TKI therapy						0.840
Yes	1/ 3 (33.3) (0.8, 90.6)	6/ 10 (60.0) (26.2, 87.8)	NE (0.05, NE) 0.317	1.75 (0.40, 7.61) 0.456	0.24 (-0.16, 0.65) 0.241	
No	18/ 64 (28.1) (17.6, 40.8)	48/113 (42.5) (33.2, 52.1)	1.78 (0.90, 3.89) 0.073	1.47 (0.94, 2.31) 0.094	0.13 (-0.01, 0.28) 0.072	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval.
Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of TSS prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to C7D1 visit, the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.
Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.2.2.3.2a
Proportion of Patients with >=4.5 Points Reduction in Domain Score of ISM-SAF at C7D1
Per Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score Patients with >= 4.5 Point Reduction at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Overall	25/ 67 (37.3) (25.8, 50.0)	45/123 (36.6) (28.1, 45.7)	0.96 (0.48, 1.94) 0.906	0.98 (0.67, 1.42) >0.999	-0.01 (-0.15, 0.14) 0.908	
Age Group (Years)						0.048
< 65	24/ 56 (42.9) (29.7, 56.8)	41/117 (35.0) (26.5, 44.4)	0.77 (0.37, 1.59) 0.427	0.86 (0.58, 1.26) >0.999	-0.06 (-0.22, 0.09) 0.438	
>= 65	1/ 11 (9.1) (0.2, 41.3)	4/ 6 (66.7) (22.3, 95.7)	NE (1.54, NE) 0.011	NE (NE, NE) NE	0.73 (0.40, 1.00) <0.0001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of domain score prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating C7D1 score, then the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

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Table 35.2.2.2.3.2a
Proportion of Patients with >=4.5 Points Reduction in Domain Score of ISM-SAF at C7D1
Per Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score Patients with >= 4.5 Point Reduction at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Sex						0.599
Male	7/ 15 (46.7) (21.3, 73.4)	13/ 35 (37.1) (21.5, 55.1)	0.71 (0.16, 3.02) 0.568	0.82 (0.42, 1.60) >0.999	-0.08 (-0.39, 0.22) 0.586	
Female	18/ 52 (34.6) (22.0, 49.1)	32/ 88 (36.4) (26.4, 47.3)	1.06 (0.47, 2.42) 0.881	1.03 (0.66, 1.62) 0.883	0.01 (-0.15, 0.18) 0.883	
Region						0.340
North America	10/ 32 (31.3) (16.1, 50.0)	20/ 52 (38.5) (25.3, 53.0)	1.36 (0.47, 4.32) 0.503	1.22 (0.68, 2.19) 0.510	0.07 (-0.15, 0.29) 0.515	
Europe	15/ 35 (42.9) (26.3, 60.6)	25/ 71 (35.2) (24.2, 47.5)	0.73 (0.27, 1.87) 0.451	0.83 (0.51, 1.35) >0.999	-0.07 (-0.27, 0.12) 0.464	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of domain score prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating C7D1 score, then the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

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Table 35.2.2.2.3.2a
Proportion of Patients with >=4.5 Points Reduction in Domain Score of ISM-SAF at C7D1
Per Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score Patients with >= 4.5 Point Reduction at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country						0.977
BEL	1/ 1 (100.0) (2.5, 100.0)	0/ 2 (0.0) (0.0, 84.2)	NE (0.05, NE) 0.317	NE (NE, NE) NE	1.00 (1.00, 1.00) NE	
CAN	0/ 5 (0.0) (0.0, 52.2)	4/ 8 (50.0) (15.7, 84.3)	NE (0.52, NE) 0.059	NE (NE, NE) NE	0.60 (0.20, 1.00) 0.004	
CHE	0/ 1 (0.0) (0.0, 97.5)	0/ 2 (0.0) (0.0, 84.2)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
DEU	9/ 14 (64.3) (35.1, 87.2)	6/ 17 (35.3) (14.2, 61.7)	0.27 (0.02, 1.80) 0.111	0.58 (0.29, 1.16) >0.999	-0.26 (-0.58, 0.05) 0.104	
DNK	0/0	1/ 1 (100.0) (2.5, 100.0)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of domain score prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating C7D1 score, then the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

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Table 35.2.2.2.3.2a
Proportion of Patients with >=4.5 Points Reduction in Domain Score of ISM-SAF at C7D1
Per Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score Patients with >= 4.5 Point Reduction at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
ESP	0/ 3 (0.0) (0.0, 70.8)	6/ 13 (46.2) (19.2, 74.9)	NE (0.32, NE) 0.118	NE (NE, NE) NE	0.44 (0.10, 0.77) 0.010	
FRA	1/ 5 (20.0) (0.5, 71.6)	4/ 10 (40.0) (12.2, 73.8)	NE (0.17, NE) 0.237	2.50 (0.39, 16.05) 0.334	0.25 (-0.07, 0.57) 0.121	
GBR	2/ 5 (40.0) (5.3, 85.3)	3/ 10 (30.0) (6.7, 65.2)	0.53 (0.03, 11.20) 0.629	0.63 (0.10, 4.07) >0.999	-0.14 (-0.68, 0.40) 0.612	
ITA	0/0	1/ 3 (33.3) (0.8, 90.6)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of domain score prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating C7D1 score, then the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

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Table 35.2.2.2.3.2a
Proportion of Patients with >=4.5 Points Reduction in Domain Score of ISM-SAF at C7D1
Per Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score Patients with >= 4.5 Point Reduction at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
NLD	0/ 3 (0.0) (0.0, 70.8)	2/ 7 (28.6) (3.7, 71.0)	NE (0.05, NE) 0.317	NE (NE, NE) NE	0.33 (-0.20, 0.87) 0.221	
NOR	1/ 2 (50.0) (1.3, 98.7)	1/ 5 (20.0) (0.5, 71.6)	0.38 (0.01, 32.70) 0.515	0.38 (0.02, 8.10) >0.999	-0.29 (-1.00, 0.62) 0.527	
SWE	1/ 1 (100.0) (2.5, 100.0)	1/ 1 (100.0) (2.5, 100.0)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
USA	10/ 27 (37.0) (19.4, 57.6)	16/ 44 (36.4) (22.4, 52.2)	1.07 (0.33, 3.65) 0.899	1.04 (0.58, 1.87) 0.898	0.01 (-0.22, 0.25) 0.901	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of domain score prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating C7D1 score, then the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

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Table 35.2.2.2.3.2a
Proportion of Patients with >=4.5 Points Reduction in Domain Score of ISM-SAF at C7D1
Per Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score Patients with >= 4.5 Point Reduction at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Baseline ISM Status						0.062
Moderate	1/ 22 (4.5) (0.1, 22.8)	8/ 37 (21.6) (9.8, 38.2)	4.09 (0.77, 323.07) 0.055	4.09 (0.76, 22.01) 0.101	0.20 (0.00, 0.39) 0.048	
Severe	24/ 45 (53.3) (37.9, 68.3)	37/ 86 (43.0) (32.4, 54.2)	0.68 (0.31, 1.47) 0.282	0.81 (0.55, 1.19) >0.999	-0.10 (-0.28, 0.08) 0.287	
Baseline Serum Tryptase (ng/mL)						0.001
< 20	10/ 13 (76.9) (46.2, 95.0)	5/ 26 (19.2) (6.6, 39.4)	0.08 (0.01, 0.56) 0.002	0.33 (0.16, 0.70) >0.999	-0.50 (-0.80, -0.21) <0.001	
>= 20	15/ 54 (27.8) (16.5, 41.6)	40/ 97 (41.2) (31.3, 51.7)	1.69 (0.76, 3.85) 0.165	1.37 (0.87, 2.17) 0.176	0.11 (-0.04, 0.26) 0.156	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of domain score prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating C7D1 score, then the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

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Table 35.2.2.2.3.2a
Proportion of Patients with >=4.5 Points Reduction in Domain Score of ISM-SAF at C7D1
Per Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score Patients with >= 4.5 Point Reduction at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
ECOG Status						0.653
0 or 1	24/ 63 (38.1) (26.1, 51.2)	41/114 (36.0) (27.2, 45.5)	0.93 (0.45, 1.92) 0.825	0.96 (0.65, 1.41) >0.999	-0.02 (-0.16, 0.13) 0.830	
2+	1/ 4 (25.0) (0.6, 80.6)	4/ 9 (44.4) (13.7, 78.8)	2.33 (0.10, 143.99) 0.544	1.67 (0.34, 8.26) 0.532	0.20 (-0.39, 0.79) 0.510	
Prior TKI therapy						0.713
Yes	1/ 3 (33.3) (0.8, 90.6)	5/ 10 (50.0) (18.7, 81.3)	0.89 (0.01, 84.88) 0.951	0.95 (0.29, 3.13) >0.999	-0.02 (-0.59, 0.55) 0.944	
No	24/ 64 (37.5) (25.7, 50.5)	40/113 (35.4) (26.6, 45.0)	0.94 (0.46, 1.92) 0.838	0.96 (0.65, 1.43) >0.999	-0.01 (-0.16, 0.13) 0.844	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of domain score prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating C7D1 score, then the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

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Table 35.2.2.2.3.2a
Proportion of Patients with >=4.5 Points Reduction in Domain Score of ISM-SAF at C7D1
Per Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Skin Domain Score Patients with >= 4.5 Point Reduction at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Overall	19/ 67 (28.4) (18.0, 40.7)	70/123 (56.9) (47.7, 65.8)	3.17 (1.62, 6.47) <0.001	1.97 (1.30, 2.98) 0.001	0.28 (0.13, 0.42) <0.001	
Age Group (Years)						0.966
< 65	16/ 56 (28.6) (17.3, 42.2)	64/117 (54.7) (45.2, 63.9)	3.01 (1.45, 6.49) 0.001	1.92 (1.22, 3.00) 0.005	0.26 (0.11, 0.41) <0.001	
>= 65	3/ 11 (27.3) (6.0, 61.0)	6/ 6 (100.0) (54.1, 100.0)	NE (2.31, NE) 0.006	7.33 (0.86, 62.60) 0.069	0.86 (0.72, 1.00) <0.0001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of domain score prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating C7D1 score, then the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

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Table 35.2.2.2.3.2a
Proportion of Patients with >=4.5 Points Reduction in Domain Score of ISM-SAF at C7D1
Per Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Skin Domain Score Patients with >= 4.5 Point Reduction at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Sex						0.526
Male	4/ 15 (26.7) (7.8, 55.1)	16/ 35 (45.7) (28.8, 63.4)	2.29 (0.50, 11.81) 0.244	1.62 (0.70, 3.77) 0.260	0.18 (-0.10, 0.45) 0.209	
Female	15/ 52 (28.8) (17.1, 43.1)	54/ 88 (61.4) (50.4, 71.6)	3.74 (1.71, 8.58) <0.001	2.15 (1.33, 3.48) 0.002	0.32 (0.16, 0.49) <0.001	
Region						0.712
North America	10/ 32 (31.3) (16.1, 50.0)	30/ 52 (57.7) (43.2, 71.3)	2.49 (0.87, 7.01) 0.060	1.66 (0.94, 2.95) 0.081	0.22 (-0.00, 0.44) 0.053	
Europe	9/ 35 (25.7) (12.5, 43.3)	40/ 71 (56.3) (44.0, 68.1)	3.82 (1.45, 10.56) 0.003	2.22 (1.22, 4.05) 0.009	0.31 (0.13, 0.50) <0.001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of domain score prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating C7D1 score, then the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

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Table 35.2.2.2.3.2a
Proportion of Patients with >=4.5 Points Reduction in Domain Score of ISM-SAF at C7D1
Per Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Skin Domain Score Patients with >= 4.5 Point Reduction at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country						0.990
BEL	1/ 1 (100.0) (2.5, 100.0)	1/ 2 (50.0) (1.3, 98.7)	0.00 (0.00, 19.00) 0.317	0.00 (NE, NE) NE	-1.00 (-1.00, -1.00) NE	
CAN	0/ 5 (0.0) (0.0, 52.2)	5/ 8 (62.5) (24.5, 91.5)	NE (0.52, NE) 0.059	NE (NE, NE) NE	0.60 (0.20, 1.00) 0.004	
CHE	0/ 1 (0.0) (0.0, 97.5)	2/ 2 (100.0) (15.8, 100.0)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
DEU	4/ 14 (28.6) (8.4, 58.1)	10/ 17 (58.8) (32.9, 81.6)	6.73 (0.83, 72.91) 0.041	2.36 (0.97, 5.74) 0.057	0.36 (0.07, 0.65) 0.016	
DNK	0/0	1/ 1 (100.0) (2.5, 100.0)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of domain score prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating C7D1 score, then the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

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Table 35.2.2.2.3.2a
Proportion of Patients with >=4.5 Points Reduction in Domain Score of ISM-SAF at C7D1
Per Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Skin Domain Score Patients with >= 4.5 Point Reduction at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
ESP	1/ 3 (33.3) (0.8, 90.6)	9/ 13 (69.2) (38.6, 90.9)	2.67 (0.12, 313.56) 0.327	2.00 (0.27, 14.76) 0.497	0.31 (-0.39, 1.00) 0.381	
FRA	1/ 5 (20.0) (0.5, 71.6)	6/ 10 (60.0) (26.2, 87.8)	7.00 (0.41, 301.51) 0.136	4.00 (0.45, 35.79) 0.215	0.50 (0.01, 0.99) 0.046	
GBR	0/ 5 (0.0) (0.0, 52.2)	5/ 10 (50.0) (18.7, 81.3)	NE (0.71, NE) 0.066	NE (NE, NE) NE	0.53 (0.19, 0.88) 0.003	
ITA	0/0	0/ 3 (0.0) (0.0, 70.8)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of domain score prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating C7D1 score, then the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

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Table 35.2.2.2.3.2a
Proportion of Patients with >=4.5 Points Reduction in Domain Score of ISM-SAF at C7D1
Per Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Skin Domain Score Patients with >= 4.5 Point Reduction at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
NLD	1/ 3 (33.3) (0.8, 90.6)	4/ 7 (57.1) (18.4, 90.1)	1.00 (0.01, 117.33) >0.999	1.00 (0.10, 9.61) >0.999	0.00 (-0.75, 0.75) >0.999	
NOR	1/ 2 (50.0) (1.3, 98.7)	1/ 5 (20.0) (0.5, 71.6)	0.38 (0.01, 32.70) 0.515	0.38 (0.02, 8.10) >0.999	-0.29 (-1.00, 0.62) 0.527	
SWE	0/ 1 (0.0) (0.0, 97.5)	1/ 1 (100.0) (2.5, 100.0)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
USA	10/ 27 (37.0) (19.4, 57.6)	25/ 44 (56.8) (41.0, 71.7)	2.00 (0.66, 5.99) 0.176	1.46 (0.82, 2.58) 0.199	0.17 (-0.07, 0.41) 0.165	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of domain score prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating C7D1 score, then the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

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Table 35.2.2.2.3.2a
Proportion of Patients with >=4.5 Points Reduction in Domain Score of ISM-SAF at C7D1
Per Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Skin Domain Score Patients with >= 4.5 Point Reduction at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Baseline ISM Status						0.960
Moderate	5/ 22 (22.7) (7.8, 45.4)	18/ 37 (48.6) (31.9, 65.6)	3.01 (0.80, 12.66) 0.069	2.03 (0.90, 4.60) 0.089	0.25 (-0.00, 0.49) 0.052	
Severe	14/ 45 (31.1) (18.2, 46.6)	52/ 86 (60.5) (49.3, 70.8)	3.23 (1.46, 7.71) 0.002	1.95 (1.20, 3.15) 0.007	0.29 (0.12, 0.46) <0.001	
Baseline Serum Tryptase (ng/mL)						0.069
< 20	6/ 13 (46.2) (19.2, 74.9)	12/ 26 (46.2) (26.6, 66.6)	0.95 (0.20, 4.62) 0.939	0.97 (0.46, 2.04) >0.999	-0.01 (-0.35, 0.33) 0.938	
>= 20	13/ 54 (24.1) (13.5, 37.6)	58/ 97 (59.8) (49.3, 69.6)	4.54 (2.03, 10.36) <0.0001	2.42 (1.47, 4.00) <0.001	0.35 (0.19, 0.50) <0.0001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of domain score prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating C7D1 score, then the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

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Table 35.2.2.2.3.2a
Proportion of Patients with >=4.5 Points Reduction in Domain Score of ISM-SAF at C7D1
Per Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Skin Domain Score Patients with >= 4.5 Point Reduction at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
ECOG Status						0.996
0 or 1	18/ 63 (28.6) (17.9, 41.3)	65/114 (57.0) (47.4, 66.3)	3.19 (1.58, 6.65) <0.001	1.98 (1.29, 3.03) 0.002	0.28 (0.13, 0.43) <0.001	
2+	1/ 4 (25.0) (0.6, 80.6)	5/ 9 (55.6) (21.2, 86.3)	4.00 (0.14, 235.38) 0.353	2.00 (0.43, 9.26) 0.375	0.30 (-0.27, 0.87) 0.303	
Prior TKI therapy						0.857
Yes	1/ 3 (33.3) (0.8, 90.6)	7/ 10 (70.0) (34.8, 93.3)	2.58 (0.15, 183.49) 0.346	2.58 (0.17, 39.11) 0.494	0.39 (-0.42, 1.00) 0.346	
No	18/ 64 (28.1) (17.6, 40.8)	63/113 (55.8) (46.1, 65.1)	3.03 (1.53, 6.42) <0.001	1.95 (1.27, 2.99) 0.002	0.27 (0.12, 0.42) <0.001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of domain score prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating C7D1 score, then the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

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Table 35.2.2.2.3.2a
Proportion of Patients with >=4.5 Points Reduction in Domain Score of ISM-SAF at C7D1
Per Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster Patients with >= 4.5 Point Reduction at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Overall	20/ 67 (29.9) (19.3, 42.3)	47/123 (38.2) (29.6, 47.4)	1.42 (0.71, 2.91) 0.286	1.25 (0.82, 1.91) 0.296	0.08 (-0.06, 0.22) 0.279	
Age Group (Years)						0.209
< 65	19/ 56 (33.9) (21.8, 47.8)	44/117 (37.6) (28.8, 47.0)	1.23 (0.59, 2.60) 0.561	1.13 (0.74, 1.74) 0.566	0.05 (-0.10, 0.19) 0.556	
>= 65	1/ 11 (9.1) (0.2, 41.3)	3/ 6 (50.0) (11.8, 88.2)	NE (0.70, NE) 0.051	13.00 (0.50, 339.18) 0.123	0.55 (0.20, 0.89) 0.002	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of domain score prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating C7D1 score, then the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

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Table 35.2.2.2.3.2a
Proportion of Patients with >=4.5 Points Reduction in Domain Score of ISM-SAF at C7D1
Per Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster Patients with >= 4.5 Point Reduction at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Sex						0.043
Male	6/ 15 (40.0) (16.3, 67.7)	8/ 35 (22.9) (10.4, 40.1)	0.35 (0.06, 1.90) 0.155	0.55 (0.25, 1.19) >0.999	-0.19 (-0.45, 0.08) 0.167	
Female	14/ 52 (26.9) (15.6, 41.0)	39/ 88 (44.3) (33.7, 55.3)	2.18 (0.97, 4.97) 0.043	1.64 (0.99, 2.72) 0.054	0.17 (0.01, 0.34) 0.033	
Region						0.367
North America	10/ 32 (31.3) (16.1, 50.0)	17/ 52 (32.7) (20.3, 47.1)	0.95 (0.32, 2.87) 0.913	0.96 (0.50, 1.85) >0.999	-0.01 (-0.22, 0.20) 0.912	
Europe	10/ 35 (28.6) (14.6, 46.3)	30/ 71 (42.3) (30.6, 54.6)	1.95 (0.73, 5.34) 0.147	1.50 (0.84, 2.65) 0.167	0.14 (-0.04, 0.33) 0.128	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of domain score prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating C7D1 score, then the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

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Table 35.2.2.2.3.2a
Proportion of Patients with >=4.5 Points Reduction in Domain Score of ISM-SAF at C7D1
Per Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster Patients with >= 4.5 Point Reduction at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country						>0.999
BEL	0/ 1 (0.0) (0.0, 97.5)	0/ 2 (0.0) (0.0, 84.2)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
CAN	1/ 5 (20.0) (0.5, 71.6)	4/ 8 (50.0) (15.7, 84.3)	2.17 (0.11, 176.61) 0.473	2.17 (0.23, 20.60) 0.501	0.28 (-0.49, 1.00) 0.474	
CHE	0/ 1 (0.0) (0.0, 97.5)	1/ 2 (50.0) (1.3, 98.7)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
DEU	5/ 14 (35.7) (12.8, 64.9)	6/ 17 (35.3) (14.2, 61.7)	1.12 (0.19, 7.20) 0.888	1.07 (0.43, 2.69) 0.884	0.02 (-0.30, 0.35) 0.883	
DNK	0/0	1/ 1 (100.0) (2.5, 100.0)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of domain score prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating C7D1 score, then the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

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Table 35.2.2.2.3.2a
Proportion of Patients with >=4.5 Points Reduction in Domain Score of ISM-SAF at C7D1
Per Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster Patients with >= 4.5 Point Reduction at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
ESP	1/ 3 (33.3) (0.8, 90.6)	6/ 13 (46.2) (19.2, 74.9)	2.00 (0.08, 130.94) 0.596	1.60 (0.23, 11.36) 0.638	0.19 (-0.46, 0.84) 0.573	
FRA	0/ 5 (0.0) (0.0, 52.2)	5/ 10 (50.0) (18.7, 81.3)	NE (0.63, NE) 0.069	NE (NE, NE) NE	0.50 (0.13, 0.87) 0.007	
GBR	1/ 5 (20.0) (0.5, 71.6)	4/ 10 (40.0) (12.2, 73.8)	2.75 (0.13, 170.00) 0.499	2.05 (0.26, 16.25) 0.497	0.20 (-0.29, 0.68) 0.425	
ITA	0/0	1/ 3 (33.3) (0.8, 90.6)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of domain score prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating C7D1 score, then the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

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Table 35.2.2.2.3.2a
Proportion of Patients with >=4.5 Points Reduction in Domain Score of ISM-SAF at C7D1
Per Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster Patients with >= 4.5 Point Reduction at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
NLD	1/ 3 (33.3) (0.8, 90.6)	2/ 7 (28.6) (3.7, 71.0)	1.00 (0.01, 117.33) >0.999	1.00 (0.10, 9.61) >0.999	0.00 (-0.75, 0.75) >0.999	
NOR	1/ 2 (50.0) (1.3, 98.7)	3/ 5 (60.0) (14.7, 94.7)	NE (0.02, NE) 0.564	1.38 (0.46, 4.07) 0.565	0.18 (-0.26, 0.62) 0.430	
SWE	1/ 1 (100.0) (2.5, 100.0)	1/ 1 (100.0) (2.5, 100.0)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
USA	9/ 27 (33.3) (16.5, 54.0)	13/ 44 (29.5) (16.8, 45.2)	0.79 (0.24, 2.65) 0.672	0.86 (0.43, 1.72) >0.999	-0.05 (-0.27, 0.18) 0.670	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of domain score prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating C7D1 score, then the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

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Table 35.2.2.2.3.2a
Proportion of Patients with >=4.5 Points Reduction in Domain Score of ISM-SAF at C7D1
Per Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster Patients with >= 4.5 Point Reduction at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Baseline ISM Status						0.623
Moderate	3/ 22 (13.6) (2.9, 34.9)	9/ 37 (24.3) (11.8, 41.2)	1.88 (0.40, 12.83) 0.365	1.67 (0.54, 5.13) 0.370	0.10 (-0.11, 0.31) 0.352	
Severe	17/ 45 (37.8) (23.8, 53.5)	38/ 86 (44.2) (33.5, 55.3)	1.31 (0.59, 2.95) 0.470	1.18 (0.75, 1.86) 0.482	0.07 (-0.11, 0.24) 0.465	
Baseline Serum Tryptase (ng/mL)						0.069
< 20	7/ 13 (53.8) (25.1, 80.8)	8/ 26 (30.8) (14.3, 51.8)	0.44 (0.09, 2.24) 0.256	0.63 (0.30, 1.35) >0.999	-0.20 (-0.53, 0.14) 0.251	
>= 20	13/ 54 (24.1) (13.5, 37.6)	39/ 97 (40.2) (30.4, 50.7)	2.00 (0.88, 4.65) 0.073	1.57 (0.94, 2.63) 0.086	0.14 (-0.01, 0.29) 0.060	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of domain score prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating C7D1 score, then the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

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Table 35.2.2.2.3.2a
Proportion of Patients with >=4.5 Points Reduction in Domain Score of ISM-SAF at C7D1
Per Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster Patients with >= 4.5 Point Reduction at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
ECOG Status						0.555
0 or 1	19/ 63 (30.2) (19.2, 43.0)	45/114 (39.5) (30.4, 49.1)	1.51 (0.74, 3.17) 0.228	1.30 (0.84, 2.00) 0.241	0.09 (-0.05, 0.23) 0.220	
2+	1/ 4 (25.0) (0.6, 80.6)	2/ 9 (22.2) (2.8, 60.0)	1.00 (0.04, 70.68) >0.999	1.00 (0.16, 6.35) >0.999	0.00 (-0.62, 0.62) >0.999	
Prior TKI therapy						0.901
Yes	1/ 3 (33.3) (0.8, 90.6)	5/ 10 (50.0) (18.7, 81.3)	NE (0.03, NE) 0.439	1.56 (0.41, 6.01) 0.516	0.18 (-0.17, 0.54) 0.315	
No	19/ 64 (29.7) (18.9, 42.4)	42/113 (37.2) (28.3, 46.8)	1.37 (0.67, 2.88) 0.347	1.23 (0.79, 1.91) 0.357	0.07 (-0.07, 0.21) 0.342	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of domain score prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating C7D1 score, then the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

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Table 35.2.3.2.2.2a
Change from Baseline in Serum Tryptase (ng/mL) by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	15	35	52	88	
Mean (StdDev)	89.07 (123.316)	59.32 (53.956)	61.73 (53.515)	56.03 (53.202)	
Median	47.00	36.50	43.60	38.80	
Min, Max	7.4, 501.6	4.2, 218.4	5.7, 235.2	3.6, 256.0	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
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Table 35.2.3.2.2.2a
Change from Baseline in Serum Tryptase (ng/mL) by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	13	34	49	81	
Mean (StdDev)	107.97 (155.578)	30.04 (30.719)	58.85 (51.548)	29.92 (34.716)	
Median	67.30	18.65	38.10	18.00	
Min, Max	7.5, 592.8	3.7, 123.0	4.9, 236.0	2.2, 196.0	
C2D1 CFB					
n	13	34	49	81	
LS Mean (StdErr) [2]	16.78 (8.174)	-24.80 (5.294)	6.09 (4.280)	-20.38 (3.666)	
95% CI [2]	0.29, 33.26	-35.48, -14.12	-2.38, 14.56	-27.63, -13.12	
Difference (95% CI) in CFB [2]		-41.57 (-59.96, -23.19)		-26.47 (-35.92, -17.01)	
p-value [3]		<0.0001		<0.0001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
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Table 35.2.3.2.2.2a
Change from Baseline in Serum Tryptase (ng/mL) by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	34	43	84	
Mean (StdDev)	93.95 (133.133)	27.99 (31.431)	62.10 (57.394)	26.37 (30.967)	
Median	40.20	14.30	38.10	18.10	
Min, Max	6.2, 536.8	4.5, 121.0	5.2, 276.0	2.0, 154.0	
C3D1 CFB					
n	15	34	43	84	
LS Mean (StdErr) [2]	12.34 (7.213)	-26.39 (4.906)	9.58 (4.788)	-22.13 (3.813)	
95% CI [2]	-2.18, 26.87	-36.27, -16.50	0.10, 19.05	-29.68, -14.58	
Difference (95% CI) in CFB [2]		-38.73 (-55.00, -22.47)		-31.71 (-42.05, -21.37)	
p-value [3]		<0.0001		<0.0001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
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Table 35.2.3.2.2.2a
Change from Baseline in Serum Tryptase (ng/mL) by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	12	32	45	82	
Mean (StdDev)	102.74 (147.840)	30.41 (36.280)	60.32 (59.077)	26.99 (34.698)	
Median	47.95	14.20	38.20	16.00	
Min, Max	7.3, 540.0	4.0, 134.0	5.2, 256.0	3.3, 162.0	
C4D1 CFB					
n	12	32	45	82	
LS Mean (StdErr) [2]	9.73 (6.036)	-21.95 (3.909)	8.97 (4.430)	-21.00 (3.631)	
95% CI [2]	-2.47, 21.93	-29.85, -14.05	0.20, 17.74	-28.18, -13.81	
Difference (95% CI) in CFB [2]		-31.68 (-45.27, -18.08)		-29.97 (-39.46, -20.48)	
p-value [3]		<0.0001		<0.0001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-pp-sex-a.sas Date: 15:41/07AUG2023

Table 35.2.3.2.2.2a
Change from Baseline in Serum Tryptase (ng/mL) by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	13	33	43	82	
Mean (StdDev)	95.85 (148.432)	34.12 (45.560)	62.63 (65.464)	24.48 (30.120)	
Median	42.70	13.90	35.00	15.45	
Min, Max	6.8, 565.6	3.9, 178.0	5.4, 280.8	2.3, 167.0	
C5D1 CFB					
n	13	33	43	82	
LS Mean (StdErr) [2]	11.55 (8.540)	-21.85 (5.545)	11.61 (5.076)	-19.55 (4.103)	
95% CI [2]	-5.69, 28.78	-33.04, -10.66	1.56, 21.65	-27.67, -11.42	
Difference (95% CI) in CFB [2]		-33.40 (-52.71, -14.08)		-31.15 (-42.24, -20.07)	
p-value [3]		0.001		<0.0001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-pp-sex-a.sas Date: 15:41/07AUG2023

Table 35.2.3.2.2.2a
Change from Baseline in Serum Tryptase (ng/mL) by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	14	33	44	77	
Mean (StdDev)	94.50 (141.676)	35.54 (49.823)	67.08 (67.839)	25.59 (29.587)	
Median	37.40	11.80	36.95	15.90	
Min, Max	6.9, 554.4	3.7, 181.0	5.3, 325.6	2.0, 143.0	
C6D1 CFB					
n	14	33	44	77	
LS Mean (StdErr) [2]	11.24 (8.748)	-19.49 (6.005)	10.97 (5.257)	-21.90 (4.373)	
95% CI [2]	-6.41, 28.88	-31.60, -7.38	0.56, 21.38	-30.56, -13.24	
Difference (95% CI) in CFB [2]		-30.73 (-50.36, -11.10)		-32.87 (-44.53, -21.21)	
p-value [3]		0.003		<0.0001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-pp-sex-a.sas Date: 15:41/07AUG2023

Table 35.2.3.2.2.2a
Change from Baseline in Serum Tryptase (ng/mL) by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	15	34	45	82	
Mean (StdDev)	96.79 (145.828)	37.72 (54.845)	68.61 (82.131)	26.97 (33.618)	
Median	39.90	12.45	38.80	15.80	
Min, Max	6.5, 590.4	4.9, 234.4	5.5, 444.0	2.1, 195.0	
C7D1 CFB					
n	15	34	45	82	
LS Mean (StdErr) [2]	12.57 (9.285)	-18.82 (6.315)	15.71 (6.963)	-22.92 (5.752)	
95% CI [2]	-6.13, 31.27	-31.54, -6.10	1.93, 29.50	-34.31, -11.54	
Difference (95% CI) in CFB [2]		-31.39 (-52.32, -10.45)		-38.64 (-53.67, -23.61)	
Hedges'G (95% CI) in CFB		-0.84 (-1.53, -0.24)		-0.76 (-1.16, -0.40)	
p-value [3]		0.004		<0.0001	0.609

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-pp-sex-a.sas Date: 15:41/07AUG2023

Table 35.2.3.2.2.3a
Change from Baseline in Serum Tryptase (ng/mL) by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	32	52	35	71	
Mean (StdDev)	53.18 (41.245)	59.78 (58.431)	81.26 (94.205)	54.90 (49.376)	
Median	44.15	38.00	39.40	39.00	
Min, Max	5.7, 159.0	3.6, 256.0	5.7, 501.6	4.2, 218.4	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-pp-reg-a.sas Date: 15:41/07AUG2023

Table 35.2.3.2.2.3a
Change from Baseline in Serum Tryptase (ng/mL) by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	27	49	35	66	
Mean (StdDev)	50.09 (40.177)	28.74 (31.376)	83.86 (106.194)	30.85 (35.122)	
Median	38.10	17.00	41.30	18.85	
Min, Max	4.9, 157.0	2.2, 165.0	5.6, 592.8	3.4, 196.0	
C2D1 CFB					
n	27	49	35	66	
LS Mean (StdErr) [2]	8.37 (6.587)	-24.41 (5.350)	7.68 (4.286)	-20.12 (3.316)	
95% CI [2]	-4.76, 21.50	-35.08, -13.75	-0.82, 16.19	-26.70, -13.54	
Difference (95% CI) in CFB [2]		-32.78 (-47.80, -17.77)		-27.80 (-37.17, -18.43)	
p-value [3]		<0.0001		<0.0001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-pp-reg-a.sas Date: 15:41/07AUG2023

Table 35.2.3.2.2.3a
Change from Baseline in Serum Tryptase (ng/mL) by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	25	50	33	68	
Mean (StdDev)	54.90 (44.098)	27.61 (32.764)	82.04 (103.172)	26.27 (29.827)	
Median	40.20	15.00	36.60	17.60	
Min, Max	5.2, 174.0	2.0, 151.0	5.8, 536.8	3.1, 154.0	
C3D1 CFB					
n	25	50	33	68	
LS Mean (StdErr) [2]	10.70 (7.133)	-25.20 (5.498)	9.05 (4.405)	-22.68 (3.273)	
95% CI [2]	-3.52, 24.93	-36.16, -14.23	0.31, 17.79	-29.17, -16.18	
Difference (95% CI) in CFB [2]		-35.90 (-51.74, -20.07)		-31.73 (-41.31, -22.14)	
p-value [3]		<0.0001		<0.0001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-pp-reg-a.sas Date: 15:41/07AUG2023

Table 35.2.3.2.2.3a
Change from Baseline in Serum Tryptase (ng/mL) by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	23	47	34	67	
Mean (StdDev)	50.00 (50.096)	30.25 (38.657)	82.28 (101.733)	26.33 (32.433)	
Median	37.80	15.10	40.65	15.60	
Min, Max	5.2, 236.0	4.6, 162.0	5.4, 540.0	3.3, 157.0	
C4D1 CFB					
n	23	47	34	67	
LS Mean (StdErr) [2]	9.26 (7.011)	-22.33 (5.556)	8.62 (3.715)	-20.99 (2.779)	
95% CI [2]	-4.74, 23.26	-33.42, -11.24	1.25, 15.99	-26.51, -15.48	
Difference (95% CI) in CFB [2]		-31.59 (-46.95, -16.23)		-29.62 (-37.69, -21.54)	
p-value [3]		<0.001		<0.0001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-pp-reg-a.sas Date: 15:41/07AUG2023

Table 35.2.3.2.2.3a
Change from Baseline in Serum Tryptase (ng/mL) by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	24	47	32	68	
Mean (StdDev)	53.12 (58.102)	26.81 (33.606)	83.26 (108.551)	27.54 (36.677)	
Median	34.40	14.30	35.45	15.95	
Min, Max	5.4, 280.8	2.3, 167.0	6.1, 565.6	3.0, 178.0	
C5D1 CFB					
n	24	47	32	68	
LS Mean (StdErr) [2]	11.16 (7.969)	-21.61 (6.122)	11.85 (4.749)	-19.20 (3.530)	
95% CI [2]	-4.74, 27.07	-33.83, -9.39	2.43, 21.28	-26.21, -12.19	
Difference (95% CI) in CFB [2]		-32.77 (-50.67, -14.87)		-31.05 (-41.41, -20.69)	
p-value [3]		<0.001		<0.0001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-pp-reg-a.sas Date: 15:41/07AUG2023

Table 35.2.3.2.2.3a
Change from Baseline in Serum Tryptase (ng/mL) by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	27	43	31	67	
Mean (StdDev)	61.20 (68.487)	29.85 (36.374)	84.58 (105.984)	27.76 (37.451)	
Median	37.70	14.20	35.40	15.90	
Min, Max	6.4, 325.6	2.0, 139.0	5.3, 554.4	2.8, 181.0	
C6D1 CFB					
n	27	43	31	67	
LS Mean (StdErr) [2]	14.10 (7.586)	-22.50 (6.360)	8.67 (5.435)	-19.45 (4.045)	
95% CI [2]	-1.04, 29.25	-35.20, -9.81	-2.13, 19.46	-27.48, -11.42	
Difference (95% CI) in CFB [2]		-36.60 (-53.83, -19.38)		-28.12 (-40.04, -16.19)	
p-value [3]		<0.0001		<0.0001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
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Table 35.2.3.2.2.3a
Change from Baseline in Serum Tryptase (ng/mL) by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	27	49	33	67	
Mean (StdDev)	62.00 (83.374)	31.49 (41.770)	86.83 (113.683)	29.12 (40.765)	
Median	39.40	14.30	38.80	16.50	
Min, Max	5.9, 444.0	2.1, 195.0	5.5, 590.4	3.5, 234.4	
C7D1 CFB					
n	27	49	33	67	
LS Mean (StdErr) [2]	17.59 (10.395)	-24.83 (8.515)	13.15 (5.907)	-18.93 (4.350)	
95% CI [2]	-3.14, 38.31	-41.80, -7.85	1.43, 24.87	-27.56, -10.29	
Difference (95% CI) in CFB [2]		-42.41 (-65.62, -19.21)		-32.08 (-44.85, -19.30)	
Hedges'G (95% CI) in CFB		-0.73 (-1.24, -0.26)		-0.91 (-1.37, -0.49)	
p-value [3]		<0.001		<0.0001	
					0.405

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-pp-reg-a.sas Date: 15:41/07AUG2023

Table 35.2.3.2.2.4a
Change from Baseline in Serum Tryptase (ng/mL) by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
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Table 35.2.3.2.2.4a
Change from Baseline in Serum Tryptase (ng/mL) by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-pp-cou-a.sas Date: 15:41/07AUG2023

Table 35.2.3.2.2.4a
Change from Baseline in Serum Tryptase (ng/mL) by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-pp-cou-a.sas Date: 15:41/07AUG2023

Table 35.2.3.2.2.4a
Change from Baseline in Serum Tryptase (ng/mL) by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-pp-cou-a.sas Date: 15:41/07AUG2023

Table 35.2.3.2.2.4a
Change from Baseline in Serum Tryptase (ng/mL) by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-pp-cou-a.sas Date: 15:41/07AUG2023

Table 35.2.3.2.2.5a
Change from Baseline in Serum Tryptase (ng/mL) by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	22	37	45	86	
Mean (StdDev)	82.26 (109.915)	53.99 (47.868)	60.81 (49.346)	58.24 (55.577)	
Median	44.15	36.40	43.50	38.50	
Min, Max	8.0, 501.6	3.6, 180.0	5.7, 159.0	5.5, 256.0	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-pp-ism-a.sas Date: 15:42/07AUG2023

Table 35.2.3.2.2.5a
Change from Baseline in Serum Tryptase (ng/mL) by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	20	35	42	80	
Mean (StdDev)	89.64 (131.181)	31.84 (40.588)	59.40 (50.226)	29.13 (30.057)	
Median	42.40	18.70	36.10	18.30	
Min, Max	8.5, 592.8	2.2, 196.0	4.9, 157.0	3.8, 165.0	
C2D1 CFB					
n	20	35	42	80	
LS Mean (StdErr) [2]	10.71 (5.600)	-18.29 (3.946)	5.94 (4.699)	-24.86 (3.791)	
95% CI [2]	-0.53, 21.95	-26.20, -10.37	-3.37, 15.24	-32.37, -17.36	
Difference (95% CI) in CFB [2]		-29.00 (-41.38, -16.61)		-30.80 (-41.71, -19.89)	
p-value [3]		<0.0001		<0.0001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-pp-ism-a.sas Date: 15:42/07AUG2023

Table 35.2.3.2.2.5a
Change from Baseline in Serum Tryptase (ng/mL) by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	18	37	40	81	
Mean (StdDev)	85.64 (127.663)	27.39 (35.573)	63.46 (54.206)	26.59 (28.872)	
Median	38.60	15.90	38.40	18.00	
Min, Max	6.2, 536.8	2.0, 154.0	5.2, 174.0	3.4, 151.0	
C3D1 CFB					
n	18	37	40	81	
LS Mean (StdErr) [2]	11.82 (5.317)	-20.89 (3.585)	9.04 (5.022)	-25.43 (3.890)	
95% CI [2]	1.16, 22.49	-28.09, -13.70	-0.90, 18.99	-33.14, -17.73	
Difference (95% CI) in CFB [2]		-32.72 (-44.32, -21.12)		-34.48 (-45.97, -22.99)	
p-value [3]		<0.0001		<0.0001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-pp-ism-a.sas Date: 15:42/07AUG2023

Table 35.2.3.2.2.5a
Change from Baseline in Serum Tryptase (ng/mL) by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	16	35	41	79	
Mean (StdDev)	84.43 (134.627)	31.03 (41.854)	63.33 (57.889)	26.58 (31.734)	
Median	38.00	15.60	39.70	15.10	
Min, Max	7.7, 540.0	3.3, 157.0	5.2, 236.0	4.4, 162.0	
C4D1 CFB					
n	16	35	41	79	
LS Mean (StdErr) [2]	10.59 (6.127)	-19.69 (4.209)	8.56 (4.211)	-22.24 (3.305)	
95% CI [2]	-1.73, 22.91	-28.15, -11.22	0.22, 16.90	-28.78, -15.69	
Difference (95% CI) in CFB [2]		-30.27 (-43.50, -17.05)		-30.80 (-40.47, -21.13)	
p-value [3]		<0.0001		<0.0001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
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Table 35.2.3.2.2.5a
Change from Baseline in Serum Tryptase (ng/mL) by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	18	36	38	79	
Mean (StdDev)	83.56 (134.092)	32.84 (50.396)	64.08 (62.619)	24.69 (25.710)	
Median	33.60	13.75	39.30	15.40	
Min, Max	9.0, 565.6	2.3, 178.0	5.4, 280.8	4.0, 110.0	
C5D1 CFB					
n	18	36	38	79	
LS Mean (StdErr) [2]	10.74 (6.504)	-15.28 (4.410)	10.61 (5.355)	-23.99 (4.099)	
95% CI [2]	-2.31, 23.80	-24.13, -6.43	0.01, 21.22	-32.11, -15.86	
Difference (95% CI) in CFB [2]		-26.02 (-40.29, -11.75)		-34.60 (-46.90, -22.29)	
p-value [3]		<0.001		<0.0001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
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Table 35.2.3.2.2.5a
Change from Baseline in Serum Tryptase (ng/mL) by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	19	32	39	78	
Mean (StdDev)	75.96 (122.138)	34.78 (50.767)	72.60 (72.212)	26.03 (29.413)	
Median	36.20	14.60	45.10	14.90	
Min, Max	8.0, 554.4	2.0, 181.0	5.3, 325.6	4.2, 126.0	
C6D1 CFB					
n	19	32	39	78	
LS Mean (StdErr) [2]	6.56 (6.426)	-15.79 (4.625)	13.36 (5.583)	-23.43 (4.322)	
95% CI [2]	-6.36, 19.48	-25.09, -6.49	2.30, 24.42	-31.99, -14.87	
Difference (95% CI) in CFB [2]		-22.35 (-36.65, -8.04)		-36.78 (-49.64, -23.93)	
p-value [3]		0.003		<0.0001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-pp-ism-a.sas Date: 15:42/07AUG2023

Table 35.2.3.2.2.5a
Change from Baseline in Serum Tryptase (ng/mL) by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	19	36	41	80	
Mean (StdDev)	86.39 (135.965)	33.35 (52.487)	70.68 (81.776)	28.67 (34.972)	
Median	39.40	14.60	38.50	14.50	
Min, Max	8.5, 590.4	2.1, 234.4	5.5, 444.0	4.4, 195.0	
C7D1 CFB					
n	19	36	41	80	
LS Mean (StdErr) [2]	13.30 (7.889)	-16.54 (5.552)	15.65 (7.017)	-24.37 (5.493)	
95% CI [2]	-2.53, 29.13	-27.68, -5.40	1.75, 29.54	-35.25, -13.49	
Difference (95% CI) in CFB [2]		-29.85 (-46.96, -12.73)		-40.02 (-56.10, -23.93)	
Hedges'G (95% CI) in CFB		-0.87 (-1.50, -0.32)		-0.83 (-1.24, -0.45)	
p-value [3]		<0.001		<0.0001	
					0.423

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-pp-ism-a.sas Date: 15:42/07AUG2023

Table 35.2.3.2.2.7a
Change from Baseline in Serum Tryptase (ng/mL) by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	63	114	4	9	
Mean (StdDev)	69.50 (76.508)	54.19 (50.751)	41.80 (24.864)	92.06 (72.884)	
Median	43.70	37.50	36.95	74.20	
Min, Max	5.7, 501.6	3.6, 256.0	21.2, 72.1	6.7, 239.2	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
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Table 35.2.3.2.2.7a
Change from Baseline in Serum Tryptase (ng/mL) by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	58	108	4	7	
Mean (StdDev)	71.12 (87.640)	27.67 (29.723)	40.58 (22.250)	65.14 (62.984)	
Median	39.70	17.75	39.10	49.50	
Min, Max	4.9, 592.8	2.2, 165.0	19.2, 64.9	4.8, 196.0	
C2D1 CFB					
n	58	108	4	7	
LS Mean (StdErr) [2]	7.70 (3.622)	-21.81 (2.844)	23.81 (36.821)	-6.68 (30.990)	
95% CI [2]	0.55, 14.85	-27.42, -16.19	-63.26, 110.88	-79.96, 66.60	
Difference (95% CI) in CFB [2]		-29.51 (-37.57, -21.44)		-30.49 (-111.93, 50.96)	
p-value [3]		<0.0001		0.405	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-pp-ecog-a.sas Date: 15:42/07AUG2023

Table 35.2.3.2.2.7a
Change from Baseline in Serum Tryptase (ng/mL) by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	54	110	4	8	
Mean (StdDev)	72.69 (86.031)	24.96 (28.838)	38.68 (19.922)	52.68 (47.630)	
Median	38.60	15.50	33.50	47.25	
Min, Max	5.2, 536.8	2.0, 151.0	21.5, 66.2	7.2, 154.0	
C3D1 CFB					
n	54	110	4	8	
LS Mean (StdErr) [2]	9.79 (3.820)	-22.98 (2.867)	25.60 (35.810)	-21.20 (28.233)	
95% CI [2]	2.24, 17.33	-28.64, -17.32	-56.98, 108.17	-86.30, 43.91	
Difference (95% CI) in CFB [2]		-32.77 (-41.16, -24.38)		-46.79 (-118.63, 25.04)	
p-value [3]		<0.0001		0.171	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
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Table 35.2.3.2.2.7a
Change from Baseline in Serum Tryptase (ng/mL) by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	53	107	4	7	
Mean (StdDev)	71.43 (88.379)	26.26 (33.057)	40.48 (20.895)	53.71 (54.481)	
Median	38.20	15.10	35.30	37.20	
Min, Max	5.2, 540.0	3.3, 162.0	22.8, 68.5	6.7, 157.0	
C4D1 CFB					
n	53	107	4	7	
LS Mean (StdErr) [2]	9.19 (3.796)	-21.57 (2.883)	12.63 (9.925)	-16.14 (7.770)	
95% CI [2]	1.70, 16.69	-27.27, -15.88	-10.84, 36.10	-34.52, 2.23	
Difference (95% CI) in CFB [2]		-30.76 (-39.02, -22.51)		-28.77 (-49.42, -8.12)	
p-value [3]		<0.0001		0.013	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
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Table 35.2.3.2.2.7a
Change from Baseline in Serum Tryptase (ng/mL) by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	52	107	4	8	
Mean (StdDev)	72.52 (93.959)	25.64 (33.112)	42.08 (23.837)	48.61 (55.993)	
Median	35.45	15.00	35.05	28.80	
Min, Max	5.4, 565.6	2.3, 178.0	23.4, 74.8	5.5, 165.6	
C5D1 CFB					
n	52	107	4	8	
LS Mean (StdErr) [2]	11.90 (4.543)	-20.28 (3.399)	13.65 (12.529)	-15.45 (9.878)	
95% CI [2]	2.92, 20.87	-27.00, -13.57	-15.24, 42.55	-38.23, 7.33	
Difference (95% CI) in CFB [2]		-32.18 (-42.22, -22.14)		-29.11 (-54.24, -3.97)	
p-value [3]		<0.0001		0.028	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
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Table 35.2.3.2.2.7a
Change from Baseline in Serum Tryptase (ng/mL) by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	102	4	8	
Mean (StdDev)	76.15 (93.261)	26.54 (35.308)	40.60 (19.408)	54.53 (48.590)	
Median	36.95	14.25	36.10	36.50	
Min, Max	5.3, 554.4	2.0, 181.0	24.4, 65.8	4.8, 143.0	
C6D1 CFB					
n	54	102	4	8	
LS Mean (StdErr) [2]	11.05 (4.366)	-20.16 (3.393)	22.14 (38.081)	-19.30 (32.185)	
95% CI [2]	2.42, 19.67	-26.86, -13.45	-65.67, 109.96	-93.51, 54.92	
Difference (95% CI) in CFB [2]		-31.20 (-40.92, -21.49)		-41.44 (-122.74, 39.86)	
p-value [3]		<0.0001		0.274	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-pp-ecog-a.sas Date: 15:42/07AUG2023

Table 35.2.3.2.2.7a
Change from Baseline in Serum Tryptase (ng/mL) by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	57	107	3	9	
Mean (StdDev)	77.31 (103.449)	28.51 (40.260)	44.30 (23.036)	49.33 (47.660)	
Median	38.80	14.20	42.00	35.60	
Min, Max	5.5, 590.4	2.1, 234.4	22.5, 68.4	5.4, 142.0	
C7D1 CFB					
n	57	107	3	9	
LS Mean (StdErr) [2]	15.37 (5.562)	-20.57 (4.327)	20.14 (44.389)	-23.05 (32.298)	
95% CI [2]	4.38, 26.35	-29.11, -12.02	-82.22, 122.50	-97.53, 51.43	
Difference (95% CI) in CFB [2]		-35.94 (-48.21, -23.66)		-43.19 (-129.19, 42.81)	
Hedges'G (95% CI) in CFB		-0.82 (-1.16, -0.49)		-0.43 (-2.04, 0.97)	
p-value [3]		<0.0001		0.280	
					0.882

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-pp-ecog-a.sas Date: 15:42/07AUG2023

Table 35.2.3.2.2.8a
Change from Baseline in Serum Tryptase (ng/mL) by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	64	113	
Mean (StdDev)	56.03 (60.393)	48.15 (31.371)	68.40 (75.584)	57.74 (54.756)	
Median	39.40	45.60	44.15	37.60	
Min, Max	5.7, 123.0	10.4, 111.0	5.7, 501.6	3.6, 256.0	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-pp-thpy-a.sas Date: 15:42/07AUG2023

Table 35.2.3.2.2.8a
Change from Baseline in Serum Tryptase (ng/mL) by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	9	59	106	
Mean (StdDev)	57.00 (65.116)	23.37 (17.368)	69.77 (86.487)	30.51 (34.465)	
Median	36.10	20.80	41.30	18.30	
Min, Max	4.9, 130.0	5.7, 51.0	5.6, 592.8	2.2, 196.0	
C2D1 CFB					
n	3	9	59	106	
LS Mean (StdErr) [2]	-0.44 (9.821)	-29.67 (8.681)	8.70 (3.945)	-21.87 (3.127)	
95% CI [2]	-23.08, 22.21	-49.69, -9.66	0.91, 16.50	-28.04, -15.69	
Difference (95% CI) in CFB [2]		-29.24 (-55.18, -3.29)		-30.57 (-39.32, -21.82)	
p-value [3]		0.032		<0.0001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-pp-thpy-a.sas Date: 15:42/07AUG2023

Table 35.2.3.2.2.8a
Change from Baseline in Serum Tryptase (ng/mL) by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	10	55	108	
Mean (StdDev)	61.77 (70.681)	22.15 (14.400)	70.81 (84.716)	27.27 (32.085)	
Median	39.10	20.10	38.10	16.40	
Min, Max	5.2, 141.0	5.7, 44.2	5.8, 536.8	2.0, 154.0	
C3D1 CFB					
n	3	10	55	108	
LS Mean (StdErr) [2]	1.55 (11.817)	-36.88 (10.452)	10.58 (4.133)	-23.54 (3.122)	
95% CI [2]	-25.19, 28.28	-60.52, -13.23	2.41, 18.74	-29.70, -17.37	
Difference (95% CI) in CFB [2]		-38.42 (-68.97, -7.87)		-34.11 (-43.15, -25.08)	
p-value [3]		0.019		<0.0001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-pp-thpy-a.sas Date: 15:42/07AUG2023

Table 35.2.3.2.2.8a
Change from Baseline in Serum Tryptase (ng/mL) by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	3	9	54	105	
Mean (StdDev)	56.27 (59.765)	20.24 (13.504)	69.98 (87.238)	28.61 (36.235)	
Median	41.60	20.90	38.00	15.10	
Min, Max	5.2, 122.0	6.1, 46.0	5.4, 540.0	3.3, 162.0	
C4D1 CFB					
n	3	9	54	105	
LS Mean (StdErr) [2]	-1.07 (12.251)	-33.01 (10.829)	9.50 (3.756)	-21.15 (2.875)	
95% CI [2]	-29.32, 27.18	-57.98, -8.04	2.08, 16.92	-26.83, -15.48	
Difference (95% CI) in CFB [2]		-31.93 (-64.30, 0.43)		-30.66 (-38.79, -22.52)	
p-value [3]		0.052		<0.0001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-pp-thpy-a.sas Date: 15:42/07AUG2023

Table 35.2.3.2.2.8a
Change from Baseline in Serum Tryptase (ng/mL) by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	8	53	107	
Mean (StdDev)	57.80 (66.786)	23.33 (14.719)	71.05 (92.609)	27.54 (36.400)	
Median	35.00	25.10	35.90	15.00	
Min, Max	5.4, 133.0	6.9, 49.2	6.1, 565.6	2.3, 178.0	
C5D1 CFB					
n	3	8	53	107	
LS Mean (StdErr) [2]	-2.10 (11.942)	-35.56 (10.545)	12.21 (4.491)	-19.96 (3.377)	
95% CI [2]	-30.34, 26.14	-60.49, -10.62	3.33, 21.08	-26.63, -13.29	
Difference (95% CI) in CFB [2]		-33.46 (-65.91, -1.00)		-32.17 (-42.03, -22.31)	
p-value [3]		0.045		<0.0001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-pp-thpy-a.sas Date: 15:42/07AUG2023

Table 35.2.3.2.2.8a
Change from Baseline in Serum Tryptase (ng/mL) by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	55	101	
Mean (StdDev)	56.93 (64.074)	21.27 (15.108)	74.61 (92.066)	29.23 (38.197)	
Median	35.40	18.80	37.70	14.50	
Min, Max	6.4, 129.0	7.3, 55.0	5.3, 554.4	2.0, 181.0	
C6D1 CFB					
n	3	9	55	101	
LS Mean (StdErr) [2]	-1.38 (12.925)	-34.27 (11.425)	11.81 (4.683)	-20.42 (3.669)	
95% CI [2]	-31.18, 28.43	-60.62, -7.93	2.56, 21.06	-27.67, -13.17	
Difference (95% CI) in CFB [2]		-32.90 (-67.04, 1.25)		-32.23 (-42.59, -21.87)	
p-value [3]		0.057		<0.0001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-pp-thpy-a.sas Date: 15:42/07AUG2023

Table 35.2.3.2.2.8a
Change from Baseline in Serum Tryptase (ng/mL) by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	9	57	107	
Mean (StdDev)	59.57 (66.527)	19.33 (13.935)	76.50 (102.973)	31.03 (42.437)	
Median	38.80	17.90	39.40	14.40	
Min, Max	5.9, 134.0	7.1, 53.3	5.5, 590.4	2.1, 234.4	
C7D1 CFB					
n	3	9	57	107	
LS Mean (StdErr) [2]	0.30 (14.159)	-38.33 (12.515)	15.91 (5.867)	-20.96 (4.545)	
95% CI [2]	-32.35, 32.95	-67.19, -9.47	4.32, 27.49	-29.93, -11.98	
Difference (95% CI) in CFB [2]		-38.63 (-76.04, -1.22)		-36.86 (-49.68, -24.04)	
Hedges'G (95% CI) in CFB		-1.01 (-2.84, 0.31)		-0.80 (-1.14, -0.47)	
p-value [3]		0.044		<0.0001	
					0.802

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-pp-thpy-a.sas Date: 15:42/07AUG2023

Table 35.2.3.3.2a
Summary of Serum Tryptase at C7D1
Per-Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >= 50% Reductions in Serum Tryptase	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Overall	0/ 67 (0.0) (0.0, 5.4)	66/123 (53.7) (44.4, 62.7)	NE (30.39, NE) <0.0001	NE (NE, NE) NE	0.56 (0.48, 0.65) <0.0001	
Age Group (Years)						0.997
< 65	0/ 56 (0.0) (0.0, 6.4)	61/117 (52.1) (42.7, 61.5)	NE (22.42, NE) <0.0001	NE (NE, NE) NE	0.54 (0.45, 0.63) <0.0001	
>= 65	0/ 11 (0.0) (0.0, 28.5)	5/ 6 (83.3) (35.9, 99.6)	NE (2.27, NE) 0.003	NE (NE, NE) NE	0.86 (0.62, 1.00) <0.0001	
Sex						>0.999
Male	0/ 15 (0.0) (0.0, 21.8)	20/ 35 (57.1) (39.4, 73.7)	NE (5.81, NE) <0.0001	NE (NE, NE) NE	0.61 (0.46, 0.77) <0.0001	
Female	0/ 52 (0.0) (0.0, 6.8)	46/ 88 (52.3) (41.4, 63.0)	NE (21.66, NE) <0.0001	NE (NE, NE) NE	0.54 (0.44, 0.65) <0.0001	

Abbreviations: CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.3.3.2a
Summary of Serum Tryptase at C7D1
Per-Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >= 50% Reductions in Serum Tryptase	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Region						>0.999
North America	0/ 32 (0.0) (0.0, 10.9)	28/ 52 (53.8) (39.5, 67.8)	NE (15.71, NE) <0.0001	NE (NE, NE) NE	0.59 (0.45, 0.73) <0.0001	
Europe	0/ 35 (0.0) (0.0, 10.0)	38/ 71 (53.5) (41.3, 65.5)	NE (12.72, NE) <0.0001	NE (NE, NE) NE	0.55 (0.43, 0.66) <0.0001	
Country						>0.999
BEL	0/ 1 (0.0) (0.0, 97.5)	0/ 2 (0.0) (0.0, 84.2)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
CAN	0/ 5 (0.0) (0.0, 52.2)	5/ 8 (62.5) (24.5, 91.5)	NE (0.88, NE) 0.035	NE (NE, NE) NE	0.84 (0.64, 1.00) <0.0001	
CHE	0/ 1 (0.0) (0.0, 97.5)	0/ 2 (0.0) (0.0, 84.2)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
DEU	0/ 14 (0.0) (0.0, 23.2)	8/ 17 (47.1) (23.0, 72.2)	NE (2.53, NE) 0.003	NE (NE, NE) NE	0.48 (0.24, 0.72) <0.0001	
DNK	0/0	0/ 1 (0.0) (0.0, 97.5)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	

Abbreviations: CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.3.3.2a
Summary of Serum Tryptase at C7D1
Per-Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >= 50% Reductions in Serum Tryptase	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
ESP	0/ 3 (0.0)	9/ 13 (69.2)	NE	NE	0.75	
	(0.0, 70.8)	(38.6, 90.9)	(0.89, NE)	(NE, NE)	(0.49, 1.00)	
			0.034	NE	<0.0001	
FRA	0/ 5 (0.0)	5/ 10 (50.0)	NE	NE	0.50	
	(0.0, 52.2)	(18.7, 81.3)	(0.63, NE)	(NE, NE)	(0.13, 0.87)	
			0.069	NE	0.007	
GBR	0/ 5 (0.0)	7/ 10 (70.0)	NE	NE	0.62	
	(0.0, 52.2)	(34.8, 93.3)	(0.91, NE)	(NE, NE)	(0.27, 0.97)	
			0.041	NE	<0.001	
ITA	0/0	1/ 3 (33.3)	NE	NE	NE	
		(0.8, 90.6)	(NE, NE)	(NE, NE)	(NE, NE)	
			NE	NE	NE	
NLD	0/ 3 (0.0)	3/ 7 (42.9)	NE	NE	0.33	
	(0.0, 70.8)	(9.9, 81.6)	(0.05, NE)	(NE, NE)	(-0.20, 0.87)	
			0.317	NE	0.221	
NOR	0/ 2 (0.0)	5/ 5 (100.0)	NE	NE	1.00	
	(0.0, 84.2)	(47.8, 100.0)	(0.71, NE)	(NE, NE)	(1.00, 1.00)	
			0.027	NE	NE	

Abbreviations: CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.3.3.2a
Summary of Serum Tryptase at C7D1
Per-Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >= 50% Reductions in Serum Tryptase	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
SWE	0/ 1 (0.0) (0.0, 97.5)	0/ 1 (0.0) (0.0, 97.5)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
USA	0/ 27 (0.0) (0.0, 12.8)	23/ 44 (52.3) (36.7, 67.5)	NE (11.09, NE) <0.0001	NE (NE, NE) NE	0.55 (0.40, 0.70) <0.0001	
Baseline ISM Status						>0.999
Moderate	0/ 22 (0.0) (0.0, 15.4)	20/ 37 (54.1) (36.9, 70.5)	NE (12.79, NE) <0.0001	NE (NE, NE) NE	0.65 (0.50, 0.80) <0.0001	
Severe	0/ 45 (0.0) (0.0, 7.9)	46/ 86 (53.5) (42.4, 64.3)	NE (15.08, NE) <0.0001	NE (NE, NE) NE	0.53 (0.42, 0.63) <0.0001	
Baseline Serum Tryptase (ng/mL)						0.997
< 20	0/ 13 (0.0) (0.0, 24.7)	6/ 26 (23.1) (9.0, 43.6)	NE (1.31, NE) 0.024	NE (NE, NE) NE	0.30 (0.12, 0.48) 0.001	
>= 20	0/ 54 (0.0) (0.0, 6.6)	60/ 97 (61.9) (51.4, 71.5)	NE (28.27, NE) <0.0001	NE (NE, NE) NE	0.63 (0.53, 0.72) <0.0001	

Abbreviations: CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.3.3.2a
Summary of Serum Tryptase at C7D1
Per-Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >= 50% Reductions in Serum Tryptase	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
ECOG Status						>0.999
0 or 1	0/ 63 (0.0) (0.0, 5.7)	62/114 (54.4) (44.8, 63.7)	NE (29.52, NE) <0.0001	NE (NE, NE) NE	0.57 (0.48, 0.66) <0.0001	
2+	0/ 4 (0.0) (0.0, 60.2)	4/ 9 (44.4) (13.7, 78.8)	NE (0.43, NE) 0.122	NE (NE, NE) NE	0.50 (0.13, 0.87) 0.008	
Prior TKI therapy						>0.999
Yes	0/ 3 (0.0) (0.0, 70.8)	5/ 10 (50.0) (18.7, 81.3)	NE (0.29, NE) 0.157	NE (NE, NE) NE	0.49 (0.14, 0.84) 0.006	
No	0/ 64 (0.0) (0.0, 5.6)	61/113 (54.0) (44.4, 63.4)	NE (28.67, NE) <0.0001	NE (NE, NE) NE	0.57 (0.48, 0.66) <0.0001	

Abbreviations: CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.4.1.2.2a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	15	35	52	88	
Mean (StdDev)	5.278 (8.6296)	1.329 (2.2605)	3.314 (7.5159)	2.916 (6.9121)	
Median	0.390	0.340	0.225	0.410	
Min, Max	0.01, 25.64	0.00, 8.65	0.01, 36.74	0.00, 41.29	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
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Table 35.2.4.1.2.2a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	13	33	48	81	
Mean (StdDev)	5.903 (8.6604)	1.034 (1.7299)	3.336 (7.7665)	2.045 (5.6915)	
Median	0.410	0.290	0.215	0.210	
Min, Max	0.01, 23.50	0.00, 6.45	0.01, 37.24	0.00, 37.93	
C2D1 CFB					
n	13	33	48	81	
LS Mean (StdErr) [2]	-0.06 (0.193)	-0.31 (0.126)	0.03 (0.169)	-0.47 (0.142)	
95% CI [2]	-0.45, 0.33	-0.57, -0.06	-0.30, 0.37	-0.75, -0.19	
Difference (95% CI) in CFB [2]		-0.25 (-0.69, 0.19)		-0.50 (-0.87, -0.13)	
p-value [3]		0.253		0.008	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
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Table 35.2.4.1.2.2a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	34	43	84	
Mean (StdDev)	5.470 (8.9534)	0.702 (1.3571)	3.171 (7.5386)	2.053 (5.7597)	
Median	0.440	0.145	0.240	0.195	
Min, Max	0.01, 26.07	0.00, 5.09	0.00, 36.89	0.00, 36.99	
C3D1 CFB					
n	15	34	43	84	
LS Mean (StdErr) [2]	0.29 (0.230)	-0.50 (0.156)	0.23 (0.272)	-0.76 (0.219)	
95% CI [2]	-0.17, 0.76	-0.82, -0.19	-0.31, 0.77	-1.19, -0.33	
Difference (95% CI) in CFB [2]		-0.80 (-1.32, -0.28)		-0.99 (-1.58, -0.40)	
p-value [3]		0.003		0.001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
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Table 35.2.4.1.2.2a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	12	31	44	82	
Mean (StdDev)	6.448 (9.2670)	0.632 (1.1573)	2.509 (6.3718)	1.868 (5.4128)	
Median	0.410	0.130	0.150	0.150	
Min, Max	0.01, 24.59	0.00, 3.96	0.00, 34.76	0.00, 38.21	
C4D1 CFB					
n	12	31	44	82	
LS Mean (StdErr) [2]	0.08 (0.331)	-0.61 (0.215)	0.21 (0.345)	-1.04 (0.279)	
95% CI [2]	-0.59, 0.75	-1.04, -0.17	-0.48, 0.89	-1.59, -0.49	
Difference (95% CI) in CFB [2]		-0.69 (-1.44, 0.06)		-1.25 (-1.98, -0.51)	
p-value [3]		0.069		0.001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
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Table 35.2.4.1.2.2a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	13	31	41	80	
Mean (StdDev)	4.294 (7.5085)	0.594 (1.1769)	1.860 (4.6286)	1.751 (5.3696)	
Median	0.420	0.120	0.170	0.140	
Min, Max	0.00, 25.53	0.00, 4.15	0.00, 26.39	0.00, 37.64	
C5D1 CFB					
n	13	31	41	80	
LS Mean (StdErr) [2]	0.14 (0.294)	-0.59 (0.194)	0.29 (0.389)	-1.08 (0.315)	
95% CI [2]	-0.46, 0.73	-0.98, -0.20	-0.48, 1.06	-1.71, -0.46	
Difference (95% CI) in CFB [2]		-0.72 (-1.40, -0.05)		-1.37 (-2.22, -0.52)	
p-value [3]		0.036		0.002	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
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Table 35.2.4.1.2.2a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	13	32	44	77	
Mean (StdDev)	6.031 (9.1098)	0.570 (1.1826)	3.211 (7.6165)	1.682 (5.4672)	
Median	0.390	0.135	0.260	0.110	
Min, Max	0.01, 25.18	0.00, 5.22	0.00, 38.37	0.00, 37.19	
C6D1 CFB					
n	13	32	44	77	
LS Mean (StdErr) [2]	0.16 (0.282)	-0.48 (0.186)	0.09 (0.344)	-1.00 (0.287)	
95% CI [2]	-0.41, 0.73	-0.86, -0.11	-0.59, 0.77	-1.57, -0.43	
Difference (95% CI) in CFB [2]		-0.64 (-1.26, -0.02)		-1.09 (-1.85, -0.32)	
p-value [3]		0.043		0.006	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
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Table 35.2.4.1.2.2a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	15	34	43	80	
Mean (StdDev)	5.273 (8.5415)	0.650 (1.1784)	2.590 (6.0387)	1.948 (5.5974)	
Median	0.380	0.155	0.210	0.115	
Min, Max	0.00, 24.24	0.00, 4.54	0.00, 28.10	0.00, 38.22	
C7D1 CFB					
n	15	34	43	80	
LS Mean (StdErr) [2]	0.14 (0.269)	-0.60 (0.183)	0.34 (0.378)	-1.07 (0.311)	
95% CI [2]	-0.40, 0.68	-0.97, -0.23	-0.41, 1.09	-1.68, -0.45	
Difference (95% CI) in CFB [2]		-0.74 (-1.35, -0.13)		-1.40 (-2.23, -0.58)	
Hedges'G (95% CI) in CFB		-0.69 (-1.36, -0.08)		-0.52 (-0.91, -0.15)	
p-value [3]		0.018		0.001	
					0.346

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-pp-sex-a.sas Date: 15:43/07AUG2023

Table 35.2.4.1.2.3a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	32	52	35	71	
Mean (StdDev)	3.889 (8.3549)	3.034 (6.7932)	3.630 (7.2828)	2.047 (5.3595)	
Median	0.310	0.420	0.180	0.290	
Min, Max	0.01, 36.74	0.00, 41.29	0.01, 25.69	0.00, 29.12	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
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Table 35.2.4.1.2.3a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	27	49	34	65	
Mean (StdDev)	4.468 (9.0525)	2.361 (6.0231)	3.419 (7.0822)	1.294 (3.8283)	
Median	0.410	0.270	0.175	0.210	
Min, Max	0.01, 37.24	0.00, 37.93	0.01, 24.98	0.00, 26.14	
C2D1 CFB					
n	27	49	34	65	
LS Mean (StdErr) [2]	0.18 (0.219)	-0.51 (0.176)	-0.16 (0.157)	-0.38 (0.121)	
95% CI [2]	-0.26, 0.61	-0.87, -0.16	-0.47, 0.15	-0.62, -0.14	
Difference (95% CI) in CFB [2]		-0.69 (-1.19, -0.20)		-0.23 (-0.57, 0.12)	
p-value [3]		0.007		0.191	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
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Table 35.2.4.1.2.3a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	25	50	33	68	
Mean (StdDev)	4.596 (9.5104)	1.911 (5.6143)	3.136 (6.5356)	1.482 (4.4195)	
Median	0.420	0.200	0.240	0.155	
Min, Max	0.00, 36.89	0.00, 36.99	0.00, 26.07	0.00, 27.54	
C3D1 CFB					
n	25	50	33	68	
LS Mean (StdErr) [2]	0.34 (0.361)	-0.88 (0.283)	0.12 (0.230)	-0.59 (0.171)	
95% CI [2]	-0.38, 1.06	-1.44, -0.31	-0.34, 0.57	-0.93, -0.25	
Difference (95% CI) in CFB [2]		-1.22 (-2.04, -0.40)		-0.71 (-1.21, -0.21)	
p-value [3]		0.004		0.006	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
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Table 35.2.4.1.2.3a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	23	46	33	67	
Mean (StdDev)	3.773 (8.3368)	1.973 (5.9049)	3.060 (6.3756)	1.224 (3.6168)	
Median	0.180	0.165	0.170	0.130	
Min, Max	0.00, 34.76	0.00, 38.21	0.00, 24.59	0.00, 23.14	
C4D1 CFB					
n	23	46	33	67	
LS Mean (StdErr) [2]	0.32 (0.425)	-0.98 (0.338)	0.05 (0.341)	-0.90 (0.251)	
95% CI [2]	-0.53, 1.16	-1.66, -0.31	-0.63, 0.73	-1.40, -0.40	
Difference (95% CI) in CFB [2]		-1.30 (-2.23, -0.36)		-0.95 (-1.69, -0.22)	
p-value [3]		0.007		0.012	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
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Table 35.2.4.1.2.3a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	23	44	31	67	
Mean (StdDev)	2.412 (5.7260)	1.845 (5.8793)	2.471 (5.3869)	1.154 (3.5891)	
Median	0.220	0.100	0.170	0.150	
Min, Max	0.00, 26.39	0.00, 37.64	0.00, 25.53	0.00, 24.06	
C5D1 CFB					
n	23	44	31	67	
LS Mean (StdErr) [2]	0.52 (0.483)	-1.14 (0.373)	0.01 (0.364)	-0.86 (0.270)	
95% CI [2]	-0.45, 1.48	-1.88, -0.39	-0.72, 0.73	-1.40, -0.33	
Difference (95% CI) in CFB [2]		-1.65 (-2.75, -0.55)		-0.87 (-1.66, -0.08)	
p-value [3]		0.004		0.031	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
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Table 35.2.4.1.2.3a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	27	43	30	66	
Mean (StdDev)	4.475 (9.3488)	1.581 (5.7720)	3.295 (6.6384)	1.208 (3.8030)	
Median	0.390	0.080	0.180	0.145	
Min, Max	0.00, 38.37	0.00, 37.19	0.00, 25.18	0.00, 25.86	
C6D1 CFB					
n	27	43	30	66	
LS Mean (StdErr) [2]	0.22 (0.378)	-0.85 (0.317)	0.01 (0.375)	-0.84 (0.276)	
95% CI [2]	-0.54, 0.97	-1.48, -0.22	-0.73, 0.76	-1.39, -0.29	
Difference (95% CI) in CFB [2]		-1.07 (-1.93, -0.21)		-0.85 (-1.67, -0.04)	
p-value [3]		0.015		0.041	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
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Table 35.2.4.1.2.3a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	27	50	31	64	
Mean (StdDev)	3.383 (7.2893)	1.948 (5.8436)	3.197 (6.4578)	1.259 (3.7260)	
Median	0.360	0.135	0.210	0.130	
Min, Max	0.00, 28.10	0.00, 38.22	0.00, 24.24	0.00, 24.80	
C7D1 CFB					
n	27	50	31	64	
LS Mean (StdErr) [2]	0.53 (0.411)	-0.94 (0.327)	-0.01 (0.385)	-0.93 (0.288)	
95% CI [2]	-0.29, 1.35	-1.59, -0.29	-0.77, 0.75	-1.50, -0.36	
Difference (95% CI) in CFB [2]		-1.48 (-2.40, -0.56)		-0.92 (-1.76, -0.08)	
Hedges'G (95% CI) in CFB		-0.65 (-1.16, -0.18)		-0.41 (-0.85, 0.02)	
p-value [3]		0.002		0.032	
					0.361

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
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Table 35.2.4.1.2.4a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
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Table 35.2.4.1.2.4a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-pp-cou-a.sas Date: 15:43/07AUG2023

Table 35.2.4.1.2.4a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
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Table 35.2.4.1.2.4a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-pp-cou-a.sas Date: 15:43/07AUG2023

Table 35.2.4.1.2.4a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-pp-cou-a.sas Date: 15:43/07AUG2023

Table 35.2.4.1.2.5a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	22	37	45	86	
Mean (StdDev)	5.067 (8.7364)	2.407 (5.8854)	3.112 (7.2442)	2.489 (6.0840)	
Median	0.790	0.290	0.230	0.420	
Min, Max	0.01, 25.69	0.00, 29.12	0.01, 36.74	0.00, 41.29	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
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Table 35.2.4.1.2.5a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	18	34	43	80	
Mean (StdDev)	5.448 (8.9685)	2.130 (5.1222)	3.228 (7.5159)	1.592 (4.8241)	
Median	1.145	0.230	0.210	0.250	
Min, Max	0.01, 24.98	0.00, 26.14	0.01, 37.24	0.00, 37.93	
C2D1 CFB					
n	18	34	43	80	
LS Mean (StdErr) [2]	-0.12 (0.292)	-0.36 (0.200)	0.11 (0.141)	-0.43 (0.115)	
95% CI [2]	-0.71, 0.46	-0.77, 0.04	-0.17, 0.39	-0.66, -0.21	
Difference (95% CI) in CFB [2]		-0.24 (-0.89, 0.41)		-0.54 (-0.87, -0.21)	
p-value [3]		0.456		0.001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
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Table 35.2.4.1.2.5a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	18	37	40	81	
Mean (StdDev)	4.568 (8.1276)	1.805 (5.2130)	3.405 (7.8905)	1.599 (4.8464)	
Median	0.815	0.120	0.245	0.210	
Min, Max	0.01, 26.07	0.00, 27.54	0.00, 36.89	0.00, 36.99	
C3D1 CFB					
n	18	37	40	81	
LS Mean (StdErr) [2]	0.21 (0.227)	-0.48 (0.153)	0.20 (0.269)	-0.86 (0.210)	
95% CI [2]	-0.25, 0.66	-0.79, -0.18	-0.34, 0.73	-1.28, -0.45	
Difference (95% CI) in CFB [2]		-0.69 (-1.19, -0.20)		-1.06 (-1.68, -0.44)	
p-value [3]		0.007		0.001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-pp-ism-a.sas Date: 15:44/07AUG2023

Table 35.2.4.1.2.5a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	15	35	41	78	
Mean (StdDev)	3.634 (6.5149)	1.549 (4.3215)	3.250 (7.4848)	1.520 (4.8519)	
Median	0.180	0.130	0.170	0.150	
Min, Max	0.01, 24.59	0.00, 23.14	0.00, 34.76	0.00, 38.21	
C4D1 CFB					
n	15	35	41	78	
LS Mean (StdErr) [2]	0.21 (0.478)	-0.76 (0.321)	0.16 (0.310)	-1.01 (0.244)	
95% CI [2]	-0.75, 1.17	-1.41, -0.12	-0.45, 0.78	-1.49, -0.53	
Difference (95% CI) in CFB [2]		-0.98 (-2.01, 0.05)		-1.17 (-1.89, -0.46)	
p-value [3]		0.063		0.001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-pp-ism-a.sas Date: 15:44/07AUG2023

Table 35.2.4.1.2.5a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	17	35	37	76	
Mean (StdDev)	3.338 (6.2913)	1.338 (4.3879)	2.036 (5.1069)	1.470 (4.7528)	
Median	0.780	0.080	0.130	0.150	
Min, Max	0.00, 25.53	0.00, 24.06	0.00, 26.39	0.00, 37.64	
C5D1 CFB					
n	17	35	37	76	
LS Mean (StdErr) [2]	0.13 (0.437)	-0.68 (0.293)	0.30 (0.368)	-1.12 (0.286)	
95% CI [2]	-0.75, 1.01	-1.27, -0.09	-0.43, 1.03	-1.69, -0.56	
Difference (95% CI) in CFB [2]		-0.81 (-1.77, 0.16)		-1.42 (-2.27, -0.57)	
p-value [3]		0.099		0.001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-pp-ism-a.sas Date: 15:44/07AUG2023

Table 35.2.4.1.2.5a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	19	31	38	78	
Mean (StdDev)	3.985 (6.9912)	1.683 (4.9906)	3.788 (8.5264)	1.226 (4.5458)	
Median	0.790	0.080	0.260	0.155	
Min, Max	0.01, 23.70	0.00, 25.86	0.00, 38.37	0.00, 37.19	
C6D1 CFB					
n	19	31	38	78	
LS Mean (StdErr) [2]	-0.16 (0.433)	-0.63 (0.314)	0.33 (0.323)	-0.89 (0.245)	
95% CI [2]	-1.04, 0.71	-1.26, 0.00	-0.31, 0.97	-1.37, -0.40	
Difference (95% CI) in CFB [2]		-0.46 (-1.44, 0.51)		-1.22 (-1.95, -0.49)	
p-value [3]		0.342		0.001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-pp-ism-a.sas Date: 15:44/07AUG2023

Table 35.2.4.1.2.5a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	19	37	39	77	
Mean (StdDev)	4.374 (7.8636)	1.531 (4.4223)	2.752 (6.2543)	1.575 (4.9432)	
Median	0.860	0.090	0.210	0.150	
Min, Max	0.01, 26.72	0.00, 24.80	0.00, 28.10	0.00, 38.22	
C7D1 CFB					
n	19	37	39	77	
LS Mean (StdErr) [2]	0.19 (0.438)	-0.69 (0.300)	0.34 (0.349)	-1.08 (0.279)	
95% CI [2]	-0.69, 1.07	-1.29, -0.09	-0.35, 1.03	-1.63, -0.53	
Difference (95% CI) in CFB [2]		-0.88 (-1.84, 0.07)		-1.42 (-2.22, -0.62)	
Hedges'G (95% CI) in CFB		-0.47 (-1.06, 0.09)		-0.60 (-1.01, -0.21)	
p-value [3]		0.070		<0.001	
					0.383

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-pp-ism-a.sas Date: 15:44/07AUG2023

Table 35.2.4.1.2.6a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	13	26	54	97	
Mean (StdDev)	0.178 (0.1556)	0.976 (2.6292)	4.615 (8.4249)	2.863 (6.5729)	
Median	0.120	0.145	0.575	0.440	
Min, Max	0.01, 0.42	0.00, 12.00	0.01, 36.74	0.00, 41.29	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-pp-tryp-a.sas Date: 15:44/07AUG2023

Table 35.2.4.1.2.6a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	48	89	
Mean (StdDev)	0.191 (0.1722)	0.415 (1.1426)	4.883 (8.7237)	2.128 (5.4590)	
Median	0.120	0.070	0.815	0.290	
Min, Max	0.01, 0.47	0.00, 5.79	0.01, 37.24	0.00, 37.93	
C2D1 CFB					
n	13	25	48	89	
LS Mean (StdErr) [2]	0.04 (0.065)	-0.11 (0.043)	-0.12 (0.155)	-0.65 (0.120)	
95% CI [2]	-0.09, 0.17	-0.20, -0.02	-0.43, 0.18	-0.89, -0.42	
Difference (95% CI) in CFB [2]		-0.15 (-0.30, 0.00)		-0.53 (-0.90, -0.16)	
p-value [3]		0.050		0.005	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-pp-tryp-a.sas Date: 15:44/07AUG2023

Table 35.2.4.1.2.6a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	26	45	92	
Mean (StdDev)	0.193 (0.1732)	0.643 (1.9817)	4.798 (8.7305)	1.952 (5.4726)	
Median	0.110	0.070	0.780	0.225	
Min, Max	0.00, 0.44	0.00, 9.71	0.00, 36.89	0.00, 36.99	
C3D1 CFB					
n	13	26	45	92	
LS Mean (StdErr) [2]	0.10 (0.190)	-0.30 (0.126)	0.13 (0.238)	-0.97 (0.175)	
95% CI [2]	-0.28, 0.49	-0.56, -0.05	-0.34, 0.60	-1.31, -0.62	
Difference (95% CI) in CFB [2]		-0.41 (-0.85, 0.04)		-1.09 (-1.66, -0.53)	
p-value [3]		0.072		<0.001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
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Table 35.2.4.1.2.6a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	12	24	44	89	
Mean (StdDev)	0.202 (0.2104)	0.611 (1.7963)	4.212 (7.9014)	1.777 (5.1652)	
Median	0.115	0.090	0.215	0.170	
Min, Max	0.00, 0.63	0.00, 8.43	0.00, 34.76	0.00, 38.21	
C4D1 CFB					
n	12	24	44	89	
LS Mean (StdErr) [2]	0.12 (0.259)	-0.39 (0.176)	0.00 (0.307)	-1.28 (0.221)	
95% CI [2]	-0.40, 0.65	-0.75, -0.03	-0.61, 0.61	-1.71, -0.84	
Difference (95% CI) in CFB [2]		-0.52 (-1.12, 0.08)		-1.28 (-2.00, -0.56)	
p-value [3]		0.090		<0.001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
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Table 35.2.4.1.2.6a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	25	42	86	
Mean (StdDev)	0.193 (0.2155)	0.530 (1.6216)	3.090 (6.0750)	1.689 (5.1565)	
Median	0.075	0.050	0.210	0.155	
Min, Max	0.00, 0.66	0.00, 7.77	0.00, 26.39	0.00, 37.64	
C5D1 CFB					
n	12	25	42	86	
LS Mean (StdErr) [2]	0.14 (0.290)	-0.42 (0.188)	0.11 (0.342)	-1.30 (0.251)	
95% CI [2]	-0.45, 0.72	-0.80, -0.04	-0.57, 0.79	-1.80, -0.81	
Difference (95% CI) in CFB [2]		-0.55 (-1.23, 0.13)		-1.41 (-2.23, -0.60)	
p-value [3]		0.107		<0.001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-pp-tryp-a.sas Date: 15:44/07AUG2023

Table 35.2.4.1.2.6a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	11	25	46	84	
Mean (StdDev)	0.180 (0.1873)	0.542 (1.6726)	4.732 (8.6741)	1.598 (5.2116)	
Median	0.100	0.100	0.590	0.135	
Min, Max	0.01, 0.47	0.00, 8.20	0.00, 38.37	0.00, 37.19	
C6D1 CFB					
n	11	25	46	84	
LS Mean (StdErr) [2]	0.13 (0.307)	-0.42 (0.196)	-0.01 (0.294)	-1.10 (0.233)	
95% CI [2]	-0.49, 0.76	-0.82, -0.02	-0.59, 0.58	-1.56, -0.64	
Difference (95% CI) in CFB [2]		-0.55 (-1.26, 0.15)		-1.10 (-1.82, -0.38)	
p-value [3]		0.121		0.003	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-pp-tryp-a.sas Date: 15:44/07AUG2023

Table 35.2.4.1.2.6a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	12	24	46	90	
Mean (StdDev)	0.219 (0.2198)	0.567 (1.7702)	4.083 (7.4393)	1.826 (5.2564)	
Median	0.120	0.065	0.590	0.205	
Min, Max	0.01, 0.57	0.00, 8.44	0.00, 28.10	0.00, 38.22	
C7D1 CFB					
n	12	24	46	90	
LS Mean (StdErr) [2]	0.17 (0.277)	-0.42 (0.183)	0.16 (0.316)	-1.25 (0.236)	
95% CI [2]	-0.40, 0.73	-0.79, -0.05	-0.47, 0.79	-1.72, -0.78	
Difference (95% CI) in CFB [2]		-0.59 (-1.25, 0.07)		-1.41 (-2.17, -0.65)	
Hedges'G (95% CI) in CFB		-0.63 (-1.41, 0.06)		-0.63 (-1.01, -0.28)	
p-value [3]		0.077		<0.001	
					0.243

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-pp-tryp-a.sas Date: 15:44/07AUG2023

Table 35.2.4.1.2.7a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	63	114	4	9	
Mean (StdDev)	3.910 (7.9564)	2.133 (5.4391)	1.298 (2.4418)	6.664 (10.4831)	
Median	0.270	0.305	0.095	0.830	
Min, Max	0.01, 36.74	0.00, 41.29	0.04, 4.96	0.01, 29.12	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-pp-ecog-a.sas Date: 15:44/07AUG2023

Table 35.2.4.1.2.7a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	57	107	4	7	
Mean (StdDev)	4.066 (8.1892)	1.405 (4.2126)	1.283 (2.4451)	7.061 (10.1640)	
Median	0.310	0.200	0.070	0.710	
Min, Max	0.01, 37.24	0.00, 37.93	0.04, 4.95	0.00, 26.14	
C2D1 CFB					
n	57	107	4	7	
LS Mean (StdErr) [2]	-0.01 (0.134)	-0.38 (0.104)	0.68 (0.874)	-1.10 (0.735)	
95% CI [2]	-0.27, 0.25	-0.59, -0.18	-1.39, 2.74	-2.84, 0.64	
Difference (95% CI) in CFB [2]		-0.37 (-0.67, -0.08)		-1.78 (-3.71, 0.15)	
p-value [3]		0.014		0.066	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
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Table 35.2.4.1.2.7a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	54	110	4	8	
Mean (StdDev)	3.944 (8.1532)	1.353 (4.2904)	1.353 (2.5651)	5.936 (9.9664)	
Median	0.305	0.145	0.085	0.360	
Min, Max	0.00, 36.89	0.00, 36.99	0.04, 5.20	0.01, 27.54	
C3D1 CFB					
n	54	110	4	8	
LS Mean (StdErr) [2]	0.22 (0.211)	-0.68 (0.159)	0.95 (1.206)	-0.61 (0.950)	
95% CI [2]	-0.20, 0.64	-0.99, -0.36	-1.83, 3.73	-2.80, 1.58	
Difference (95% CI) in CFB [2]		-0.90 (-1.36, -0.43)		-1.56 (-3.98, 0.85)	
p-value [3]		<0.001		0.174	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
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Table 35.2.4.1.2.7a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	52	106	4	7	
Mean (StdDev)	3.500 (7.4077)	1.267 (4.2279)	1.443 (2.7317)	5.491 (8.6949)	
Median	0.215	0.130	0.085	0.340	
Min, Max	0.00, 34.76	0.00, 38.21	0.06, 5.54	0.06, 23.14	
C4D1 CFB					
n	52	106	4	7	
LS Mean (StdErr) [2]	0.14 (0.262)	-0.84 (0.197)	1.84 (2.159)	-1.61 (1.690)	
95% CI [2]	-0.38, 0.66	-1.23, -0.45	-3.26, 6.95	-5.61, 2.38	
Difference (95% CI) in CFB [2]		-0.98 (-1.55, -0.41)		-3.46 (-7.95, 1.04)	
p-value [3]		<0.001		0.112	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-pp-ecog-a.sas Date: 15:44/07AUG2023

Table 35.2.4.1.2.7a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	51	103	3	8	
Mean (StdDev)	2.485 (5.6091)	1.160 (4.1415)	1.787 (2.9561)	4.885 (8.4239)	
Median	0.200	0.120	0.100	0.435	
Min, Max	0.00, 26.39	0.00, 37.64	0.06, 5.20	0.00, 24.06	
C5D1 CFB					
n	51	103	3	8	
LS Mean (StdErr) [2]	0.23 (0.287)	-0.87 (0.217)	1.61 (2.637)	-1.37 (1.904)	
95% CI [2]	-0.34, 0.79	-1.29, -0.44	-4.63, 7.84	-5.87, 3.13	
Difference (95% CI) in CFB [2]		-1.09 (-1.73, -0.45)		-2.98 (-8.26, 2.31)	
p-value [3]		<0.001		0.225	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
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Table 35.2.4.1.2.7a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	53	101	4	8	
Mean (StdDev)	4.037 (8.2304)	1.060 (4.0767)	1.430 (2.7333)	5.085 (8.9517)	
Median	0.340	0.100	0.065	0.515	
Min, Max	0.00, 38.37	0.00, 37.19	0.06, 5.53	0.01, 25.86	
C6D1 CFB					
n	53	101	4	8	
LS Mean (StdErr) [2]	0.06 (0.255)	-0.75 (0.197)	1.46 (2.257)	-1.55 (1.908)	
95% CI [2]	-0.44, 0.57	-1.14, -0.36	-3.75, 6.66	-5.95, 2.85	
Difference (95% CI) in CFB [2]		-0.82 (-1.38, -0.25)		-3.01 (-7.82, 1.81)	
p-value [3]		0.005		0.188	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
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Table 35.2.4.1.2.7a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	55	106	3	8	
Mean (StdDev)	3.360 (6.9484)	1.299 (4.2782)	1.890 (3.1438)	5.034 (8.7474)	
Median	0.290	0.120	0.100	0.395	
Min, Max	0.00, 28.10	0.00, 38.22	0.05, 5.52	0.02, 24.80	
C7D1 CFB					
n	55	106	3	8	
LS Mean (StdErr) [2]	0.25 (0.276)	-0.86 (0.214)	1.65 (2.414)	-1.23 (1.743)	
95% CI [2]	-0.29, 0.80	-1.28, -0.44	-4.06, 7.36	-5.35, 2.90	
Difference (95% CI) in CFB [2]		-1.11 (-1.73, -0.50)		-2.87 (-7.71, 1.96)	
Hedges'G (95% CI) in CFB		-0.51 (-0.85, -0.19)		-0.55 (-2.27, 0.85)	
p-value [3]		<0.001		0.203	
					0.268

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
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Table 35.2.4.1.2.8a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	64	113	
Mean (StdDev)	4.240 (5.4904)	5.149 (12.8807)	3.731 (7.8754)	2.227 (5.0194)	
Median	2.240	0.420	0.245	0.340	
Min, Max	0.03, 10.45	0.01, 41.29	0.01, 36.74	0.00, 29.12	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
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Table 35.2.4.1.2.8a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	9	58	105	
Mean (StdDev)	4.487 (5.9569)	5.074 (12.4613)	3.852 (8.0898)	1.468 (3.6176)	
Median	2.190	0.290	0.230	0.230	
Min, Max	0.02, 11.25	0.01, 37.93	0.01, 37.24	0.00, 26.14	
C2D1 CFB					
n	3	9	58	105	
LS Mean (StdErr) [2]	0.23 (0.694)	-0.61 (0.614)	0.01 (0.137)	-0.41 (0.107)	
95% CI [2]	-1.37, 1.84	-2.02, 0.81	-0.26, 0.28	-0.62, -0.19	
Difference (95% CI) in CFB [2]		-0.84 (-2.68, 0.99)		-0.41 (-0.71, -0.11)	
p-value [3]		0.321		0.008	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
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Table 35.2.4.1.2.8a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	10	55	108	
Mean (StdDev)	4.317 (5.6280)	4.227 (11.5658)	3.735 (8.0549)	1.426 (3.8460)	
Median	2.230	0.250	0.250	0.155	
Min, Max	0.03, 10.69	0.00, 36.99	0.00, 36.89	0.00, 27.54	
C3D1 CFB					
n	3	10	55	108	
LS Mean (StdErr) [2]	-0.00 (0.934)	-1.04 (0.826)	0.27 (0.212)	-0.67 (0.161)	
95% CI [2]	-2.12, 2.11	-2.91, 0.83	-0.15, 0.68	-0.99, -0.35	
Difference (95% CI) in CFB [2]		-1.04 (-3.45, 1.38)		-0.94 (-1.40, -0.47)	
p-value [3]		0.357		<0.001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
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Table 35.2.4.1.2.8a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	2	9	54	104	
Mean (StdDev)	5.395 (7.6155)	4.739 (12.5984)	3.277 (7.2295)	1.251 (3.2339)	
Median	5.395	0.170	0.175	0.135	
Min, Max	0.01, 10.78	0.00, 38.21	0.00, 34.76	0.00, 23.14	
C4D1 CFB					
n	2	9	54	104	
LS Mean (StdErr) [2]	0.55 (1.235)	-0.92 (0.824)	0.22 (0.279)	-0.90 (0.214)	
95% CI [2]	-2.37, 3.47	-2.86, 1.03	-0.33, 0.77	-1.32, -0.48	
Difference (95% CI) in CFB [2]		-1.46 (-4.13, 1.20)		-1.12 (-1.73, -0.52)	
p-value [3]		0.235		<0.001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
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Table 35.2.4.1.2.8a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	8	51	103	
Mean (StdDev)	4.183 (5.5391)	5.145 (13.1708)	2.344 (5.5154)	1.140 (3.1558)	
Median	2.060	0.085	0.200	0.140	
Min, Max	0.02, 10.47	0.01, 37.64	0.00, 26.39	0.00, 24.06	
C5D1 CFB					
n	3	8	51	103	
LS Mean (StdErr) [2]	-0.18 (1.017)	-1.17 (0.898)	0.31 (0.308)	-0.92 (0.232)	
95% CI [2]	-2.58, 2.23	-3.29, 0.95	-0.30, 0.92	-1.38, -0.46	
Difference (95% CI) in CFB [2]		-1.00 (-3.76, 1.77)		-1.22 (-1.90, -0.54)	
p-value [3]		0.422		<0.001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-pp-thpy-a.sas Date: 15:44/07AUG2023

Table 35.2.4.1.2.8a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	54	100	
Mean (StdDev)	4.427 (5.8851)	4.519 (12.2792)	3.822 (8.1262)	1.071 (3.2389)	
Median	2.150	0.140	0.260	0.120	
Min, Max	0.02, 11.11	0.00, 37.19	0.00, 38.37	0.00, 25.86	
C6D1 CFB					
n	3	9	54	100	
LS Mean (StdErr) [2]	0.01 (1.055)	-1.43 (0.933)	0.15 (0.276)	-0.78 (0.214)	
95% CI [2]	-2.42, 2.45	-3.58, 0.72	-0.40, 0.69	-1.20, -0.35	
Difference (95% CI) in CFB [2]		-1.44 (-4.23, 1.34)		-0.93 (-1.53, -0.32)	
p-value [3]		0.267		0.003	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
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Table 35.2.4.1.2.8a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	9	55	105	
Mean (StdDev)	4.437 (5.9539)	4.671 (12.6133)	3.221 (6.8826)	1.294 (3.3881)	
Median	2.070	0.130	0.240	0.140	
Min, Max	0.03, 11.21	0.00, 38.22	0.00, 28.10	0.00, 24.80	
C7D1 CFB					
n	3	9	55	105	
LS Mean (StdErr) [2]	-0.01 (0.894)	-1.36 (0.790)	0.33 (0.294)	-0.89 (0.227)	
95% CI [2]	-2.07, 2.05	-3.18, 0.47	-0.25, 0.91	-1.34, -0.44	
Difference (95% CI) in CFB [2]		-1.34 (-3.70, 1.02)		-1.22 (-1.87, -0.58)	
Hedges'G (95% CI) in CFB		-0.56 (-2.21, 0.82)		-0.53 (-0.87, -0.21)	
p-value [3]		0.226		<0.001	
					0.949

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-pp-thpy-a.sas Date: 15:44/07AUG2023

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Protocol: BLU-285-2203
CSR Germany

Table 35.2.4.3.2a
Summary of KIT D816V Mutation Allele Fraction in Blood at C7D1
Per-Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1 with detectable mutation at Baseline, Part 2 (Part 2 Baseline)

Patients with >= 50% Reductions in KIT D816V MAF or undetectable (<0.02%) for patients with detectable mutation at Baseline	Placebo (N=61) n/N (%) (95% CIs)	Avapritinib 25 mg (N=103) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Overall	4/ 61 (6.6) (1.8, 15.9)	70/103 (68.0) (58.0, 76.8)	41.06 (10.46, 146.26) <0.0001	11.42 (4.15, 31.43) <0.0001	0.62 (0.51, 0.73) <0.0001	
Age Group (Years)						0.950
< 65	4/ 50 (8.0) (2.2, 19.2)	64/ 97 (66.0) (55.7, 75.3)	28.55 (7.41, 103.23) <0.0001	8.55 (3.24, 22.54) <0.0001	0.58 (0.46, 0.70) <0.0001	
>= 65	0/ 11 (0.0) (0.0, 28.5)	6/ 6 (100.0) (54.1, 100.0)	NE (3.85, NE) <0.001	NE (NE, NE) NE	1.00 (1.00, 1.00) NE	
Sex						0.039
Male	3/ 14 (21.4) (4.7, 50.8)	20/ 30 (66.7) (47.2, 82.7)	5.67 (1.02, 34.83) 0.024	2.84 (0.98, 8.19) 0.053	0.39 (0.10, 0.68) 0.008	
Female	1/ 47 (2.1) (0.1, 11.3)	50/ 73 (68.5) (56.6, 78.9)	265.20 (17.98, 6038.36) <0.0001	41.65 (4.60, 377.08) <0.001	0.68 (0.57, 0.79) <0.0001	

Abbreviations: CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with detectable mutation at Baseline will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.4.3.2a
Summary of KIT D816V Mutation Allele Fraction in Blood at C7D1
Per-Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1 with detectable mutation at Baseline, Part 2 (Part 2 Baseline)

Patients with >= 50% Reductions in KIT D816V MAF or undetectable (<0.02%) for patients with detectable mutation at Baseline	Placebo (N=61) n/N (%) (95% CIs)	Avapritinib 25 mg (N=103) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Region						0.390
North America	3/ 29 (10.3) (2.2, 27.4)	29/ 41 (70.7) (54.5, 83.9)	28.59 (4.65, 241.05) <0.0001	7.25 (2.29, 22.94) <0.001	0.61 (0.42, 0.79) <0.0001	
Europe	1/ 32 (3.1) (0.1, 16.2)	41/ 62 (66.1) (53.0, 77.7)	80.98 (8.71, 2652.34) <0.0001	23.85 (3.06, 185.95) 0.002	0.64 (0.51, 0.77) <0.0001	
Country						>0.999
BEL	0/ 1 (0.0) (0.0, 97.5)	1/ 2 (50.0) (1.3, 98.7)	NE (NE, NE) NE	NE (NE, NE) NE	0.00 (0.00, 0.00) NE	
CAN	0/ 5 (0.0) (0.0, 52.2)	4/ 4 (100.0) (39.8, 100.0)	NE (0.21, NE) 0.046	NE (NE, NE) NE	1.00 (1.00, 1.00) NE	
CHE	0/ 1 (0.0) (0.0, 97.5)	0/ 1 (0.0) (0.0, 97.5)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
DEU	1/ 13 (7.7) (0.2, 36.0)	11/ 17 (64.7) (38.3, 85.8)	25.82 (1.78, 803.40) 0.003	9.27 (1.18, 72.86) 0.034	0.57 (0.30, 0.83) <0.0001	
DNK	0/0	0/ 1 (0.0) (0.0, 97.5)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	

Abbreviations: CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with detectable mutation at Baseline will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.4.3.2a
Summary of KIT D816V Mutation Allele Fraction in Blood at C7D1
Per-Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1 with detectable mutation at Baseline, Part 2 (Part 2 Baseline)

Patients with >= 50% Reductions in KIT D816V MAF or undetectable (<0.02%) for patients with detectable mutation at Baseline	Placebo (N=61) n/N (%) (95% CIs)	Avapritinib 25 mg (N=103) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
ESP	0/ 3 (0.0) (0.0, 70.8)	7/ 10 (70.0) (34.8, 93.3)	NE (0.80, NE) 0.039	NE (NE, NE) NE	0.85 (0.65, 1.00) <0.0001	
FRA	0/ 5 (0.0) (0.0, 52.2)	7/ 9 (77.8) (40.0, 97.2)	NE (1.95, NE) 0.008	NE (NE, NE) NE	0.83 (0.52, 1.00) <0.0001	
GBR	0/ 4 (0.0) (0.0, 60.2)	8/ 9 (88.9) (51.8, 99.7)	NE (2.31, NE) 0.006	NE (NE, NE) NE	0.90 (0.73, 1.00) <0.0001	
ITA	0/0	0/ 1 (0.0) (0.0, 97.5)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
NLD	0/ 2 (0.0) (0.0, 84.2)	3/ 7 (42.9) (9.9, 81.6)	NE (0.04, NE) 0.414	NE (NE, NE) NE	0.33 (-0.20, 0.87) 0.221	
NOR	0/ 2 (0.0) (0.0, 84.2)	3/ 4 (75.0) (19.4, 99.4)	NE (0.30, NE) 0.134	NE (NE, NE) NE	0.75 (0.33, 1.00) <0.001	

Abbreviations: CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with detectable mutation at Baseline will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.4.3.2a
Summary of KIT D816V Mutation Allele Fraction in Blood at C7D1
Per-Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1 with detectable mutation at Baseline, Part 2 (Part 2 Baseline)

Patients with >= 50% Reductions in KIT D816V MAF or undetectable (<0.02%) for patients with detectable mutation at Baseline	Placebo (N=61) n/N (%) (95% CIs)	Avapritinib 25 mg (N=103) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
SWE	0/ 1 (0.0) (0.0, 97.5)	1/ 1 (100.0) (2.5, 100.0)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
USA	3/ 24 (12.5) (2.7, 32.4)	25/ 37 (67.6) (50.2, 82.0)	19.84 (3.14, 169.02) <0.0001	5.49 (1.83, 16.46) 0.002	0.54 (0.34, 0.74) <0.0001	
Baseline ISM Status						0.316
Moderate	3/ 21 (14.3) (3.0, 36.3)	22/ 30 (73.3) (54.1, 87.7)	19.77 (3.36, 129.82) <0.0001	5.47 (1.81, 16.54) 0.003	0.62 (0.39, 0.84) <0.0001	
Severe	1/ 40 (2.5) (0.1, 13.2)	48/ 73 (65.8) (53.7, 76.5)	78.77 (10.72, 3072.43) <0.0001	25.22 (3.70, 171.71) <0.001	0.62 (0.50, 0.75) <0.0001	
Baseline Serum Tryptase (ng/mL)						0.978
< 20	0/ 10 (0.0) (0.0, 30.8)	12/ 21 (57.1) (34.0, 78.2)	NE (2.10, NE) 0.006	NE (NE, NE) NE	0.52 (0.27, 0.77) <0.0001	
>= 20	4/ 51 (7.8) (2.2, 18.9)	58/ 82 (70.7) (59.6, 80.3)	35.52 (9.30, 136.06) <0.0001	9.98 (3.65, 27.30) <0.0001	0.64 (0.52, 0.76) <0.0001	

Abbreviations: CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with detectable mutation at Baseline will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.4.3.2a
Summary of KIT D816V Mutation Allele Fraction in Blood at C7D1
Per-Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1 with detectable mutation at Baseline, Part 2 (Part 2 Baseline)

Patients with >= 50% Reductions in KIT D816V MAF or undetectable (<0.02%) for patients with detectable mutation at Baseline	Placebo (N=61) n/N (%) (95% CIs)	Avapritinib 25 mg (N=103) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
ECOG Status						0.977
0 or 1	4/ 57 (7.0) (1.9, 17.0)	65/ 95 (68.4) (58.1, 77.6)	41.62 (10.09, 151.81) <0.0001	10.74 (3.93, 29.40) <0.0001	0.62 (0.51, 0.74) <0.0001	
2+	0/ 4 (0.0) (0.0, 60.2)	5/ 8 (62.5) (24.5, 91.5)	NE (0.63, NE) 0.069	NE (NE, NE) NE	0.60 (0.23, 0.97) 0.002	
Prior TKI therapy						0.979
Yes	0/ 3 (0.0) (0.0, 70.8)	4/ 6 (66.7) (22.3, 95.7)	NE (0.34, NE) 0.117	NE (NE, NE) NE	0.73 (0.40, 1.00) <0.0001	
No	4/ 58 (6.9) (1.9, 16.7)	66/ 97 (68.0) (57.8, 77.1)	38.76 (9.92, 140.82) <0.0001	10.66 (3.91, 29.05) <0.0001	0.62 (0.50, 0.73) <0.0001	

Abbreviations: CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with detectable mutation at Baseline will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-resp-pp-a.sas Date: 14:56/14APR2023

Table 35.2.5.1.2.1a
Change from Baseline in Bone Marrow Mast Cells by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	56	117	11	6	
Mean (StdDev)	10.7 (11.81)	10.8 (10.66)	18.8 (13.83)	17.3 (16.71)	
Median	5.5	7.0	15.0	10.0	
Min, Max	1, 70	1, 50	3, 40	7, 50	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.6
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-bm-sum-g-pp-age-a.sas Date: 15:45/07AUG2023

Table 35.2.5.1.2.1a
Change from Baseline in Bone Marrow Mast Cells by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	48	98	9	6	
Mean (StdDev)	9.4 (9.73)	7.4 (11.36)	14.1 (10.94)	6.7 (6.65)	
Median	6.0	4.0	10.0	5.0	
Min, Max	1, 60	1, 90	5, 40	2, 20	
C7D1 CFB					
n	48	98	9	6	
LS Mean (StdErr) [2]	-0.13 (1.482)	-1.61 (1.060)	-5.19 (5.266)	-8.51 (6.871)	
95% CI [2]	-3.06, 2.80	-3.70, 0.49	-16.66, 6.28	-23.48, 6.46	
Difference (95% CI) in CFB [2]		-1.47 (-4.68, 1.73)		-3.32 (-23.28, 16.64)	
Hedges'G (95% CI) in CFB		-0.14 (-0.49, 0.21)		-0.19 (-1.37, 0.91)	
p-value [3]		0.364		0.723	
					0.492

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.6
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Table 35.2.5.1.2.2a
Change from Baseline in Bone Marrow Mast Cells by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	15	35	52	88	
Mean (StdDev)	14.9 (18.37)	12.3 (12.42)	11.2 (10.20)	10.6 (10.45)	
Median	10.0	7.0	7.0	7.0	
Min, Max	1, 70	1, 40	2, 40	1, 50	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.6
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Table 35.2.5.1.2.2a
Change from Baseline in Bone Marrow Mast Cells by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	13	30	44	74	
Mean (StdDev)	12.8 (15.65)	8.8 (10.73)	9.3 (7.65)	6.7 (11.29)	
Median	7.0	5.0	7.0	4.0	
Min, Max	1, 60	1, 40	1, 40	1, 90	
C7D1 CFB					
n	13	30	44	74	
LS Mean (StdErr) [2]	-1.71 (2.711)	-2.69 (1.789)	0.30 (1.757)	-1.17 (1.416)	
95% CI [2]	-7.19, 3.78	-6.30, 0.93	-3.18, 3.78	-3.98, 1.63	
Difference (95% CI) in CFB [2]		-0.98 (-6.96, 5.00)		-1.47 (-5.30, 2.36)	
Hedges'G (95% CI) in CFB		-0.10 (-0.77, 0.57)		-0.12 (-0.50, 0.25)	
p-value [3]		0.742		0.449	
					0.919

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.6
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-bm-sum-g-pp-sex-a.sas Date: 15:45/07AUG2023

Table 35.2.5.1.2.3a
Change from Baseline in Bone Marrow Mast Cells by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	32	52	35	71	
Mean (StdDev)	10.8 (8.62)	10.5 (10.52)	13.1 (15.13)	11.5 (11.43)	
Median	8.5	7.0	5.0	5.0	
Min, Max	2, 40	1, 50	1, 70	1, 50	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.6
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Table 35.2.5.1.2.3a
Change from Baseline in Bone Marrow Mast Cells by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	25	45	32	59	
Mean (StdDev)	8.1 (4.97)	8.1 (14.70)	11.7 (12.45)	6.8 (7.41)	
Median	7.0	4.0	7.0	5.0	
Min, Max	1, 20	1, 90	1, 60	1, 40	
C7D1 CFB					
n	25	45	32	59	
LS Mean (StdErr) [2]	-1.53 (2.854)	-0.60 (2.279)	0.51 (1.430)	-2.69 (1.044)	
95% CI [2]	-7.23, 4.17	-5.15, 3.96	-2.33, 3.35	-4.76, -0.61	
Difference (95% CI) in CFB [2]		0.94 (-5.34, 7.21)		-3.20 (-6.32, -0.08)	
Hedges'G (95% CI) in CFB		0.06 (-0.43, 0.56)		-0.39 (-0.84, 0.04)	
p-value [3]		0.767		0.045	
					0.223

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.6
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Table 35.2.5.1.2.4a
Change from Baseline in Bone Marrow Mast Cells by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.6
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Table 35.2.5.1.2.4a
Change from Baseline in Bone Marrow Mast Cells by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.6
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Table 35.2.5.1.2.4a
Change from Baseline in Bone Marrow Mast Cells by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.6
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-bm-sum-g-pp-cou-a.sas Date: 15:45/07AUG2023

Table 35.2.5.1.2.4a
Change from Baseline in Bone Marrow Mast Cells by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.6
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Table 35.2.5.1.2.4a
Change from Baseline in Bone Marrow Mast Cells by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.6
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Table 35.2.5.1.2.5a
Change from Baseline in Bone Marrow Mast Cells by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	22	37	45	86	
Mean (StdDev)	13.5 (16.59)	12.5 (12.65)	11.3 (9.92)	10.5 (10.27)	
Median	8.5	5.0	7.0	7.0	
Min, Max	1, 70	1, 50	2, 40	1, 50	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.6
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Table 35.2.5.1.2.5a
Change from Baseline in Bone Marrow Mast Cells by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	18	34	39	70	
Mean (StdDev)	13.6 (14.70)	10.1 (16.63)	8.5 (6.46)	6.0 (6.85)	
Median	8.5	5.0	5.0	3.0	
Min, Max	1, 60	1, 90	1, 30	1, 40	
C7D1 CFB					
n	18	34	39	70	
LS Mean (StdErr) [2]	1.58 (4.014)	-1.16 (2.692)	-1.89 (1.213)	-2.71 (0.952)	
95% CI [2]	-6.49, 9.65	-6.57, 4.25	-4.29, 0.51	-4.59, -0.82	
Difference (95% CI) in CFB [2]		-2.74 (-11.25, 5.76)		-0.82 (-3.62, 1.98)	
Hedges'G (95% CI) in CFB		-0.17 (-0.76, 0.41)		-0.10 (-0.50, 0.29)	
p-value [3]		0.520		0.564	
					0.557

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.6
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Table 35.2.5.1.2.6a
Change from Baseline in Bone Marrow Mast Cells by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	13	26	54	97	
Mean (StdDev)	3.7 (1.32)	2.8 (2.08)	14.1 (13.06)	13.3 (11.39)	
Median	3.0	2.5	10.0	10.0	
Min, Max	2, 5	1, 10	1, 70	2, 50	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.6
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Table 35.2.5.1.2.6a
Change from Baseline in Bone Marrow Mast Cells by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	10	25	47	79	
Mean (StdDev)	3.6 (2.59)	2.8 (2.01)	11.5 (10.43)	8.8 (12.39)	
Median	3.0	3.0	10.0	5.0	
Min, Max	1, 10	1, 10	1, 60	1, 90	
C7D1 CFB					
n	10	25	47	79	
LS Mean (StdErr) [2]	0.25 (0.676)	0.12 (0.398)	-1.99 (1.629)	-3.68 (1.294)	
95% CI [2]	-1.12, 1.63	-0.69, 0.93	-5.21, 1.24	-6.24, -1.12	
Difference (95% CI) in CFB [2]		-0.14 (-1.65, 1.38)		-1.69 (-5.71, 2.32)	
Hedges'G (95% CI) in CFB		-0.07 (-0.83, 0.69)		-0.15 (-0.52, 0.21)	
p-value [3]		0.857		0.405	
					0.763

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.6
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Table 35.2.5.1.2.7a
Change from Baseline in Bone Marrow Mast Cells by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	63	114	4	9	
Mean (StdDev)	12.0 (12.65)	10.7 (10.73)	12.0 (9.27)	15.7 (14.17)	
Median	7.0	7.0	10.0	10.0	
Min, Max	1, 70	1, 50	3, 25	4, 50	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.6
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Table 35.2.5.1.2.7a
Change from Baseline in Bone Marrow Mast Cells by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	54	97	3	7	
Mean (StdDev)	10.2 (10.25)	7.4 (11.40)	9.0 (1.73)	6.6 (6.60)	
Median	7.0	4.0	10.0	5.0	
Min, Max	1, 60	1, 90	7, 10	1, 20	
C7D1 CFB					
n	54	97	3	7	
LS Mean (StdErr) [2]	-0.12 (1.538)	-1.81 (1.172)	-5.83 (4.154)	-3.06 (3.248)	
95% CI [2]	-3.16, 2.92	-4.13, 0.50	-16.00, 4.33	-11.00, 4.89	
Difference (95% CI) in CFB [2]		-1.69 (-5.07, 1.69)		2.78 (-6.19, 11.74)	
Hedges'G (95% CI) in CFB		-0.15 (-0.48, 0.19)		0.30 (-1.20, 2.01)	
p-value [3]		0.324		0.477	
					0.561

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.6
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-bm-sum-g-pp-ecog-a.sas Date: 15:46/07AUG2023

Table 35.2.5.1.2.8a
Change from Baseline in Bone Marrow Mast Cells by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	64	113	
Mean (StdDev)	8.3 (5.77)	10.7 (11.40)	12.2 (12.64)	11.1 (11.04)	
Median	5.0	7.0	7.0	7.0	
Min, Max	5, 15	3, 40	1, 70	1, 50	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.6
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-bm-sum-g-pp-thpy-a.sas Date: 15:46/07AUG2023

Table 35.2.5.1.2.8a
Change from Baseline in Bone Marrow Mast Cells by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	7	54	97	
Mean (StdDev)	8.3 (5.77)	8.0 (10.07)	10.2 (10.19)	7.3 (11.24)	
Median	5.0	3.0	7.0	5.0	
Min, Max	5, 15	2, 30	1, 60	1, 90	
C7D1 CFB					
n	3	7	54	97	
LS Mean (StdErr) [2]	3.16 (3.980)	6.31 (3.510)	-0.43 (1.537)	-2.09 (1.168)	
95% CI [2]	-6.58, 12.90	-2.28, 14.90	-3.47, 2.60	-4.39, 0.22	
Difference (95% CI) in CFB [2]		3.15 (-8.09, 14.40)		-1.65 (-4.99, 1.68)	
Hedges'G (95% CI) in CFB		0.33 (-1.17, 2.04)		-0.14 (-0.48, 0.19)	
p-value [3]		0.518		0.329	
					0.725

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.6
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-bm-sum-g-pp-thpy-a.sas Date: 15:46/07AUG2023

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CSR Germany

Table 35.2.5.2.2a
Summary of Bone Marrow Mast Cells at C7D1
Per-Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1 with aggregates at Baseline, Part 2 (Part 2 Baseline)

Patients with >= 50% Reductions in Bone Marrow MCs or no aggregates for patients with aggregates at Baseline	Placebo (N=54) n/N (%) (95% CIs)	Avapritinib 25 mg (N=91) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Overall	13/ 54 (24.1) (13.5, 37.6)	47/ 91 (51.6) (40.9, 62.3)	4.01 (1.69, 9.75) <0.001	2.36 (1.37, 4.06) 0.002	0.30 (0.15, 0.45) <0.0001	
Age Group (Years)						0.942
< 65	10/ 44 (22.7) (11.5, 37.8)	43/ 85 (50.6) (39.5, 61.6)	4.62 (1.73, 13.30) <0.001	2.58 (1.37, 4.86) 0.003	0.32 (0.16, 0.47) <0.0001	
>= 65	3/ 10 (30.0) (6.7, 65.2)	4/ 6 (66.7) (22.3, 95.7)	2.18 (0.11, 44.02) 0.483	1.42 (0.61, 3.34) 0.418	0.22 (-0.40, 0.83) 0.491	
Sex						0.065
Male	5/ 12 (41.7) (15.2, 72.3)	12/ 26 (46.2) (26.6, 66.6)	1.47 (0.28, 8.42) 0.612	1.22 (0.56, 2.63) 0.614	0.09 (-0.24, 0.42) 0.597	
Female	8/ 42 (19.0) (8.6, 34.1)	35/ 65 (53.8) (41.0, 66.3)	5.89 (2.05, 18.90) <0.001	3.16 (1.54, 6.51) 0.002	0.37 (0.20, 0.53) <0.0001	

Abbreviations: CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with aggregates at Baseline will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.5.2.2a
Summary of Bone Marrow Mast Cells at C7D1
Per-Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1 with aggregates at Baseline, Part 2 (Part 2 Baseline)

Patients with >= 50% Reductions in Bone Marrow MCs or no aggregates for patients with aggregates at Baseline	Placebo (N=54) n/N (%) (95% CIs)	Avapritinib 25 mg (N=91) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Region						0.239
North America	9/ 26 (34.6) (17.2, 55.7)	23/ 40 (57.5) (40.9, 73.0)	2.67 (0.79, 9.00) 0.081	1.66 (0.91, 3.03) 0.095	0.22 (-0.01, 0.46) 0.062	
Europe	4/ 28 (14.3) (4.0, 32.7)	24/ 51 (47.1) (32.9, 61.5)	7.06 (1.66, 36.83) 0.002	4.16 (1.37, 12.69) 0.012	0.36 (0.18, 0.54) <0.001	
Country						0.955
BEL	1/ 1 (100.0) (2.5, 100.0)	0/ 2 (0.0) (0.0, 84.2)	0.00 (0.00, 19.00) 0.317	0.00 (NE, NE) NE	-1.00 (-1.00, -1.00) NE	
CAN	1/ 5 (20.0) (0.5, 71.6)	6/ 8 (75.0) (34.9, 96.8)	NE (0.11, NE) 0.157	2.33 (0.34, 15.80) 0.385	0.32 (-0.17, 0.81) 0.199	
CHE	0/0	0/ 1 (0.0) (0.0, 97.5)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
DEU	1/ 12 (8.3) (0.2, 38.5)	4/ 10 (40.0) (12.2, 73.8)	NE (1.05, NE) 0.031	NE (NE, NE) NE	0.40 (0.10, 0.70) 0.010	
DNK	0/0	0/ 1 (0.0) (0.0, 97.5)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	

Abbreviations: CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with aggregates at Baseline will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.5.2.2a
Summary of Bone Marrow Mast Cells at C7D1
Per-Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1 with aggregates at Baseline, Part 2 (Part 2 Baseline)

Patients with >= 50% Reductions in Bone Marrow MCs or no aggregates for patients with aggregates at Baseline	Placebo (N=54) n/N (%) (95% CIs)	Avapritinib 25 mg (N=91) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
ESP	0/ 3 (0.0) (0.0, 70.8)	8/ 11 (72.7) (39.0, 94.0)	NE (0.72, NE) 0.050	NE (NE, NE) NE	0.72 (0.42, 1.00) <0.0001	
FRA	1/ 3 (33.3) (0.8, 90.6)	4/ 7 (57.1) (18.4, 90.1)	4.00 (0.03, 391.00) 0.462	1.60 (0.37, 6.85) 0.526	0.30 (-0.48, 1.00) 0.449	
GBR	1/ 5 (20.0) (0.5, 71.6)	3/ 7 (42.9) (9.9, 81.6)	1.17 (0.01, 91.57) 0.919	1.17 (0.04, 32.71) 0.928	0.03 (-0.51, 0.57) 0.916	
ITA	0/0	0/ 1 (0.0) (0.0, 97.5)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
NLD	0/ 2 (0.0) (0.0, 84.2)	1/ 5 (20.0) (0.5, 71.6)	NE (0.04, NE) 0.414	NE (NE, NE) NE	0.33 (-0.20, 0.87) 0.221	
NOR	0/ 2 (0.0) (0.0, 84.2)	4/ 5 (80.0) (28.4, 99.5)	NE (0.41, NE) 0.090	NE (NE, NE) NE	0.82 (0.51, 1.00) <0.0001	

Abbreviations: CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with aggregates at Baseline will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.5.2.2a
Summary of Bone Marrow Mast Cells at C7D1
Per-Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1 with aggregates at Baseline, Part 2 (Part 2 Baseline)

Patients with >= 50% Reductions in Bone Marrow MCs or no aggregates for patients with aggregates at Baseline	Placebo (N=54) n/N (%) (95% CIs)	Avapritinib 25 mg (N=91) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
SWE	0/0	0/ 1 (0.0) (0.0, 97.5)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
USA	8/ 21 (38.1) (18.1, 61.6)	17/ 32 (53.1) (34.7, 70.9)	1.87 (0.52, 6.76) 0.299	1.40 (0.74, 2.66) 0.299	0.15 (-0.12, 0.42) 0.274	
Baseline ISM Status						0.457
Moderate	2/ 16 (12.5) (1.6, 38.3)	15/ 30 (50.0) (31.3, 68.7)	6.45 (1.12, 64.95) 0.017	3.93 (0.99, 15.66) 0.052	0.36 (0.12, 0.61) 0.004	
Severe	11/ 38 (28.9) (15.4, 45.9)	32/ 61 (52.5) (39.3, 65.4)	3.37 (1.23, 9.68) 0.009	2.02 (1.13, 3.63) 0.018	0.27 (0.09, 0.46) 0.004	
Baseline Serum Tryptase (ng/mL)						0.894
< 20	4/ 8 (50.0) (15.7, 84.3)	6/ 8 (75.0) (34.9, 96.8)	3.90 (0.25, 216.24) 0.263	1.73 (0.62, 4.83) 0.300	0.32 (-0.16, 0.79) 0.198	
>= 20	9/ 46 (19.6) (9.4, 33.9)	41/ 83 (49.4) (38.2, 60.6)	4.03 (1.61, 10.47) <0.001	2.52 (1.35, 4.69) 0.004	0.30 (0.14, 0.45) <0.001	

Abbreviations: CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with aggregates at Baseline will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.5.2.2a
Summary of Bone Marrow Mast Cells at C7D1
Per-Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1 with aggregates at Baseline, Part 2 (Part 2 Baseline)

Patients with >= 50% Reductions in Bone Marrow MCs or no aggregates for patients with aggregates at Baseline	Placebo (N=54) n/N (%) (95% CIs)	Avapritinib 25 mg (N=91) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
ECOG Status						0.262
0 or 1	12/ 51 (23.5) (12.8, 37.5)	45/ 84 (53.6) (42.4, 64.5)	4.55 (1.83, 11.59) <0.001	2.52 (1.43, 4.46) 0.001	0.33 (0.17, 0.48) <0.0001	
2+	1/ 3 (33.3) (0.8, 90.6)	2/ 7 (28.6) (3.7, 71.0)	0.83 (0.03, 58.90) 0.899	0.87 (0.11, 6.79) >0.999	-0.05 (-0.73, 0.63) 0.896	
Prior TKI therapy						0.501
Yes	1/ 2 (50.0) (1.3, 98.7)	4/ 9 (44.4) (13.7, 78.8)	NE (0.03, NE) 0.439	1.75 (0.32, 9.55) 0.518	0.27 (-0.14, 0.69) 0.199	
No	12/ 52 (23.1) (12.5, 36.8)	43/ 82 (52.4) (41.1, 63.6)	4.10 (1.69, 10.06) <0.001	2.44 (1.38, 4.32) 0.002	0.31 (0.15, 0.46) <0.0001	

Abbreviations: CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with aggregates at Baseline will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.9.2.2.2a
Change from Baseline of EQ-5D-5L VAS by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	14	32	50	87	
Mean (StdDev)	48.4 (19.32)	56.4 (17.08)	57.6 (17.07)	55.3 (17.45)	
Median	47.5	56.5	60.0	55.0	
Min, Max	15, 75	20, 93	19, 94	15, 93	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-pp-sex-a.sas Date: 15:55/07AUG2023

Table 35.2.9.2.2.2a
Change from Baseline of EQ-5D-5L VAS by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	13	33	51	86	
Mean (StdDev)	50.5 (17.11)	61.7 (17.68)	58.9 (16.90)	57.0 (18.14)	
Median	58.0	65.0	65.0	59.5	
Min, Max	15, 72	20, 87	10, 81	20, 90	
C2D1 CFB					
n	13	31	49	85	
LS Mean (StdErr) [2]	1.66 (4.389)	4.03 (2.904)	1.21 (2.193)	1.83 (1.835)	
95% CI [2]	-7.22, 10.53	-1.84, 9.90	-3.13, 5.55	-1.80, 5.46	
Difference (95% CI) in CFB [2]		2.38 (-7.26, 12.01)		0.62 (-4.07, 5.31)	
p-value [3]		0.621		0.794	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-pp-sex-a.sas Date: 15:55/07AUG2023

Table 35.2.9.2.2.2a
Change from Baseline of EQ-5D-5L VAS by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	28	48	82	
Mean (StdDev)	48.8 (22.82)	65.6 (14.78)	60.4 (17.39)	61.9 (18.85)	
Median	51.0	70.0	64.5	65.0	
Min, Max	12, 84	30, 95	15, 90	14, 96	
C3D1 CFB					
n	14	28	46	81	
LS Mean (StdErr) [2]	-1.33 (4.672)	12.08 (3.281)	2.47 (2.619)	6.59 (2.115)	
95% CI [2]	-10.78, 8.13	5.43, 18.72	-2.71, 7.66	2.40, 10.78	
Difference (95% CI) in CFB [2]		13.40 (3.06, 23.74)		4.12 (-1.45, 9.68)	
p-value [3]		0.012		0.146	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-pp-sex-a.sas Date: 15:55/07AUG2023

Table 35.2.9.2.2.2a
Change from Baseline of EQ-5D-5L VAS by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	13	30	43	83	
Mean (StdDev)	46.1 (16.30)	65.7 (15.38)	57.3 (17.76)	62.0 (19.41)	
Median	42.0	68.5	60.0	64.0	
Min, Max	22, 70	25, 95	19, 91	10, 91	
C4D1 CFB					
n	12	29	41	82	
LS Mean (StdErr) [2]	-0.50 (4.310)	11.63 (2.976)	1.32 (3.134)	6.80 (2.457)	
95% CI [2]	-9.23, 8.23	5.60, 17.66	-4.88, 7.53	1.94, 11.67	
Difference (95% CI) in CFB [2]		12.13 (2.79, 21.47)		5.48 (-1.03, 12.00)	
p-value [3]		0.012		0.098	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-pp-sex-a.sas Date: 15:55/07AUG2023

Table 35.2.9.2.2.2a
Change from Baseline of EQ-5D-5L VAS by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	31	45	78	
Mean (StdDev)	50.8 (20.12)	64.5 (15.68)	57.6 (17.90)	59.7 (19.63)	
Median	52.0	68.0	60.0	63.0	
Min, Max	18, 90	30, 90	10, 90	19, 93	
C5D1 CFB					
n	14	28	44	77	
LS Mean (StdErr) [2]	-0.51 (4.297)	6.48 (3.037)	0.33 (2.988)	4.41 (2.427)	
95% CI [2]	-9.21, 8.19	0.34, 12.63	-5.59, 6.24	-0.40, 9.21	
Difference (95% CI) in CFB [2]		6.99 (-2.44, 16.43)		4.08 (-2.33, 10.49)	
p-value [3]		0.142		0.210	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-pp-sex-a.sas Date: 15:55/07AUG2023

Table 35.2.9.2.2.2a
Change from Baseline of EQ-5D-5L VAS by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	13	32	45	79	
Mean (StdDev)	44.8 (18.58)	66.5 (15.50)	56.2 (18.93)	60.8 (20.17)	
Median	44.0	69.0	58.0	65.0	
Min, Max	16, 75	25, 97	15, 96	13, 95	
C6D1 CFB					
n	12	29	44	78	
LS Mean (StdErr) [2]	-2.98 (4.254)	9.68 (2.844)	-0.32 (2.951)	5.47 (2.396)	
95% CI [2]	-11.60, 5.64	3.92, 15.44	-6.16, 5.53	0.72, 10.21	
Difference (95% CI) in CFB [2]		12.66 (3.39, 21.93)		5.79 (-0.58, 12.15)	
p-value [3]		0.009		0.074	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-pp-sex-a.sas Date: 15:55/07AUG2023

Table 35.2.9.2.2.2a
Change from Baseline of EQ-5D-5L VAS by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	14	34	44	77	
Mean (StdDev)	46.8 (22.29)	66.7 (12.47)	58.2 (18.69)	62.2 (21.10)	
Median	44.0	70.0	57.0	65.0	
Min, Max	16, 86	26, 91	17, 97	5, 95	
C7D1 CFB					
n	13	31	43	76	
LS Mean (StdErr) [2]	-3.64 (4.516)	10.99 (2.954)	1.19 (3.178)	6.50 (2.563)	
95% CI [2]	-12.77, 5.49	5.02, 16.96	-5.11, 7.48	1.42, 11.57	
Difference (95% CI) in CFB [2]		14.63 (4.80, 24.46)		5.31 (-1.36, 11.98)	
Hedges'G (95% CI) in CFB		0.88 (0.23, 1.62)		0.24 (-0.13, 0.63)	
p-value [3]		0.005		0.118	
					0.159

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-pp-sex-a.sas Date: 15:55/07AUG2023

Table 35.2.9.2.2.3a
Change from Baseline of EQ-5D-5L VAS by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	30	49	34	70	
Mean (StdDev)	62.1 (14.76)	61.6 (16.16)	49.9 (18.54)	51.4 (16.92)	
Median	65.0	65.0	54.5	50.0	
Min, Max	30, 91	30, 93	15, 94	15, 81	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-pp-reg-a.sas Date: 15:55/07AUG2023

Table 35.2.9.2.2.3a
Change from Baseline of EQ-5D-5L VAS by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	29	51	35	68	
Mean (StdDev)	61.3 (15.13)	63.8 (16.66)	53.8 (18.15)	54.2 (18.09)	
Median	65.0	65.0	58.0	53.0	
Min, Max	25, 81	20, 90	10, 80	20, 90	
C2D1 CFB					
n	28	48	34	68	
LS Mean (StdErr) [2]	-1.50 (2.980)	1.29 (2.480)	3.66 (2.628)	3.21 (1.978)	
95% CI [2]	-7.44, 4.44	-3.65, 6.24	-1.56, 8.87	-0.71, 7.14	
Difference (95% CI) in CFB [2]		2.79 (-3.79, 9.37)		-0.45 (-6.02, 5.13)	
p-value [3]		0.400		0.874	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-pp-reg-a.sas Date: 15:55/07AUG2023

Table 35.2.9.2.2.3a
Change from Baseline of EQ-5D-5L VAS by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	29	44	34	66	
Mean (StdDev)	63.6 (16.02)	65.4 (17.67)	52.5 (20.52)	61.2 (18.01)	
Median	69.0	68.5	60.0	66.0	
Min, Max	20, 85	30, 91	12, 90	14, 96	
C3D1 CFB					
n	27	43	33	66	
LS Mean (StdErr) [2]	1.72 (3.543)	5.69 (2.981)	1.84 (2.987)	9.86 (2.188)	
95% CI [2]	-5.35, 8.79	-0.26, 11.64	-4.09, 7.77	5.51, 14.20	
Difference (95% CI) in CFB [2]		3.97 (-3.85, 11.80)		8.02 (1.67, 14.36)	
p-value [3]		0.315		0.014	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-pp-reg-a.sas Date: 15:55/07AUG2023

Table 35.2.9.2.2.3a
Change from Baseline of EQ-5D-5L VAS by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	22	44	34	69	
Mean (StdDev)	59.9 (18.81)	68.4 (16.45)	51.3 (16.77)	59.6 (18.90)	
Median	61.0	70.5	52.5	60.0	
Min, Max	22, 90	10, 91	19, 91	11, 95	
C4D1 CFB					
n	20	43	33	68	
LS Mean (StdErr) [2]	0.68 (3.865)	8.59 (3.099)	2.24 (3.346)	8.53 (2.450)	
95% CI [2]	-7.06, 8.41	2.39, 14.79	-4.40, 8.88	3.66, 13.39	
Difference (95% CI) in CFB [2]		7.91 (-0.10, 15.93)		6.28 (-0.79, 13.36)	
p-value [3]		0.053		0.081	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-pp-reg-a.sas Date: 15:55/07AUG2023

Table 35.2.9.2.2.3a
Change from Baseline of EQ-5D-5L VAS by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	26	41	34	68	
Mean (StdDev)	60.5 (20.52)	66.8 (15.36)	52.5 (16.35)	57.6 (19.71)	
Median	63.0	70.0	54.0	62.0	
Min, Max	10, 90	31, 90	16, 80	19, 93	
C5D1 CFB					
n	25	38	33	67	
LS Mean (StdErr) [2]	-1.21 (3.536)	4.69 (2.996)	1.55 (3.411)	5.21 (2.517)	
95% CI [2]	-8.29, 5.86	-1.31, 10.68	-5.22, 8.32	0.21, 10.21	
Difference (95% CI) in CFB [2]		5.90 (-1.98, 13.78)		3.66 (-3.57, 10.89)	
p-value [3]		0.140		0.317	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-pp-reg-a.sas Date: 15:55/07AUG2023

Table 35.2.9.2.2.3a
Change from Baseline of EQ-5D-5L VAS by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	24	44	34	67	
Mean (StdDev)	56.7 (19.74)	69.2 (14.59)	51.4 (18.96)	58.0 (20.41)	
Median	61.0	70.0	50.0	60.0	
Min, Max	15, 91	40, 91	20, 96	13, 97	
C6D1 CFB					
n	23	41	33	66	
LS Mean (StdErr) [2]	-4.29 (3.542)	7.04 (2.936)	2.61 (3.297)	6.77 (2.415)	
95% CI [2]	-11.38, 2.79	1.17, 12.91	-3.94, 9.15	1.97, 11.56	
Difference (95% CI) in CFB [2]		11.33 (3.46, 19.21)		4.16 (-2.84, 11.16)	
p-value [3]		0.006		0.241	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-pp-reg-a.sas Date: 15:55/07AUG2023

Table 35.2.9.2.2.3a
Change from Baseline of EQ-5D-5L VAS by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	24	44	34	67	
Mean (StdDev)	62.9 (20.02)	70.3 (14.66)	50.1 (18.53)	59.2 (20.21)	
Median	65.0	73.0	50.0	61.0	
Min, Max	16, 93	30, 91	17, 97	5, 95	
C7D1 CFB					
n	23	41	33	66	
LS Mean (StdErr) [2]	-2.01 (3.670)	7.43 (2.939)	2.19 (3.579)	8.42 (2.622)	
95% CI [2]	-9.35, 5.33	1.55, 13.31	-4.92, 9.29	3.21, 13.62	
Difference (95% CI) in CFB [2]		9.44 (1.71, 17.17)		6.23 (-1.37, 13.83)	
Hedges'G (95% CI) in CFB		0.51 (-0.00, 1.05)		0.29 (-0.12, 0.73)	
p-value [3]		0.017		0.107	
					0.611

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-pp-reg-a.sas Date: 15:55/07AUG2023

Table 35.2.9.2.2.4a
Change from Baseline of EQ-5D-5L VAS by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-pp-cou-a.sas Date: 15:55/07AUG2023

Table 35.2.9.2.2.4a
Change from Baseline of EQ-5D-5L VAS by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-pp-cou-a.sas Date: 15:55/07AUG2023

Table 35.2.9.2.2.4a
Change from Baseline of EQ-5D-5L VAS by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-pp-cou-a.sas Date: 15:55/07AUG2023

Table 35.2.9.2.2.4a
Change from Baseline of EQ-5D-5L VAS by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-pp-cou-a.sas Date: 15:55/07AUG2023

Table 35.2.9.2.2.4a
Change from Baseline of EQ-5D-5L VAS by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-pp-cou-a.sas Date: 15:55/07AUG2023

Table 35.2.9.2.2.5a
Change from Baseline of EQ-5D-5L VAS by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	20	35	44	84	
Mean (StdDev)	61.3 (19.10)	60.8 (16.78)	53.0 (16.83)	53.4 (17.12)	
Median	66.5	62.0	55.0	50.0	
Min, Max	19, 94	20, 93	15, 90	15, 93	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-pp-ism-a.sas Date: 15:56/07AUG2023

Table 35.2.9.2.2.5a
Change from Baseline of EQ-5D-5L VAS by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	20	35	44	84	
Mean (StdDev)	60.8 (17.62)	63.5 (17.16)	55.6 (16.87)	56.2 (18.09)	
Median	62.5	68.0	60.0	60.0	
Min, Max	10, 81	30, 90	15, 78	20, 90	
C2D1 CFB					
n	19	34	43	82	
LS Mean (StdErr) [2]	1.38 (4.000)	3.40 (2.586)	2.06 (2.202)	2.19 (1.781)	
95% CI [2]	-6.65, 9.41	-1.79, 8.60	-2.30, 6.42	-1.33, 5.72	
Difference (95% CI) in CFB [2]		2.03 (-6.11, 10.16)		0.14 (-4.96, 5.23)	
p-value [3]		0.619		0.958	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
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Table 35.2.9.2.2.5a
Change from Baseline of EQ-5D-5L VAS by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	18	33	45	77	
Mean (StdDev)	60.3 (20.67)	70.3 (14.16)	56.5 (18.82)	59.7 (18.48)	
Median	64.5	70.0	60.0	61.0	
Min, Max	15, 90	30, 95	12, 85	14, 96	
C3D1 CFB					
n	16	33	44	76	
LS Mean (StdErr) [2]	1.05 (4.777)	11.59 (2.942)	2.22 (2.450)	6.38 (2.027)	
95% CI [2]	-8.57, 10.66	5.67, 17.51	-2.64, 7.07	2.37, 10.40	
Difference (95% CI) in CFB [2]		10.54 (0.76, 20.32)		4.17 (-1.56, 9.90)	
p-value [3]		0.035		0.153	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
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Table 35.2.9.2.2.5a
Change from Baseline of EQ-5D-5L VAS by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	17	33	39	80	
Mean (StdDev)	61.9 (16.71)	70.3 (12.40)	51.6 (17.75)	60.0 (19.69)	
Median	60.0	69.0	50.0	64.0	
Min, Max	26, 91	50, 95	19, 90	10, 91	
C4D1 CFB					
n	15	32	38	79	
LS Mean (StdErr) [2]	1.51 (4.313)	11.71 (2.751)	0.45 (3.019)	6.01 (2.322)	
95% CI [2]	-7.18, 10.21	6.17, 17.26	-5.53, 6.43	1.41, 10.61	
Difference (95% CI) in CFB [2]		10.20 (1.73, 18.67)		5.56 (-1.27, 12.39)	
p-value [3]		0.019		0.110	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
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Table 35.2.9.2.2.5a
Change from Baseline of EQ-5D-5L VAS by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	32	41	77	
Mean (StdDev)	59.0 (14.79)	66.1 (15.00)	54.5 (20.06)	59.0 (19.69)	
Median	61.0	67.0	59.0	63.0	
Min, Max	25, 81	41, 90	10, 90	19, 93	
C5D1 CFB					
n	17	30	41	75	
LS Mean (StdErr) [2]	-3.08 (4.649)	5.69 (3.014)	1.52 (2.823)	4.78 (2.241)	
95% CI [2]	-12.45, 6.29	-0.39, 11.76	-4.07, 7.12	0.34, 9.22	
Difference (95% CI) in CFB [2]		8.76 (-0.74, 18.27)		3.26 (-3.28, 9.80)	
p-value [3]		0.070		0.325	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
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Table 35.2.9.2.2.5a
Change from Baseline of EQ-5D-5L VAS by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	19	33	39	78	
Mean (StdDev)	58.8 (19.40)	68.6 (14.62)	51.1 (18.97)	59.9 (20.17)	
Median	61.0	70.0	50.0	65.0	
Min, Max	22, 96	40, 97	15, 91	13, 95	
C6D1 CFB					
n	17	31	39	76	
LS Mean (StdErr) [2]	-5.78 (4.439)	7.32 (2.867)	0.13 (2.870)	6.03 (2.235)	
95% CI [2]	-14.72, 3.16	1.55, 13.10	-5.55, 5.82	1.60, 10.46	
Difference (95% CI) in CFB [2]		13.10 (4.10, 22.10)		5.89 (-0.74, 12.53)	
p-value [3]		0.005		0.081	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
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Table 35.2.9.2.2.5a
Change from Baseline of EQ-5D-5L VAS by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	18	35	40	76	
Mean (StdDev)	60.9 (19.20)	69.8 (13.18)	52.9 (20.12)	60.7 (20.52)	
Median	58.5	70.0	50.5	65.0	
Min, Max	30, 97	30, 91	16, 93	5, 95	
C7D1 CFB					
n	16	33	40	74	
LS Mean (StdErr) [2]	-1.74 (4.304)	9.43 (2.714)	-0.24 (3.096)	6.29 (2.452)	
95% CI [2]	-10.40, 6.92	3.97, 14.89	-6.38, 5.89	1.43, 11.15	
Difference (95% CI) in CFB [2]		11.17 (2.56, 19.78)		6.53 (-0.54, 13.61)	
Hedges'G (95% CI) in CFB		0.68 (0.08, 1.34)		0.32 (-0.07, 0.71)	
p-value [3]		0.012		0.070	
					0.504

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-pp-ism-a.sas Date: 15:56/07AUG2023

Table 35.2.9.2.2.6a
Change from Baseline of EQ-5D-5L VAS by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	11	25	53	94	
Mean (StdDev)	61.5 (15.00)	53.1 (18.95)	54.4 (18.26)	56.3 (16.86)	
Median	61.0	60.0	59.0	55.0	
Min, Max	40, 90	20, 81	15, 94	15, 93	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-pp-tryp-a.sas Date: 15:56/07AUG2023

Table 35.2.9.2.2.6a
Change from Baseline of EQ-5D-5L VAS by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	12	25	52	94	
Mean (StdDev)	57.9 (16.98)	58.8 (20.17)	57.0 (17.34)	58.2 (17.57)	
Median	63.0	65.0	60.0	60.0	
Min, Max	20, 75	25, 90	10, 81	20, 90	
C2D1 CFB					
n	11	24	51	92	
LS Mean (StdErr) [2]	-4.15 (4.059)	4.68 (2.326)	2.88 (1.974)	1.95 (1.561)	
95% CI [2]	-12.42, 4.12	-0.06, 9.42	-1.02, 6.79	-1.14, 5.03	
Difference (95% CI) in CFB [2]		8.83 (-0.09, 17.75)		-0.94 (-5.76, 3.89)	
p-value [3]		0.052		0.702	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-pp-tryp-a.sas Date: 15:56/07AUG2023

Table 35.2.9.2.2.6a
Change from Baseline of EQ-5D-5L VAS by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	24	50	86	
Mean (StdDev)	60.6 (15.93)	60.5 (17.00)	56.8 (20.12)	63.6 (18.19)	
Median	66.0	66.5	61.0	68.0	
Min, Max	30, 85	30, 85	12, 90	14, 96	
C3D1 CFB					
n	11	24	49	85	
LS Mean (StdErr) [2]	1.44 (5.438)	9.18 (3.116)	3.33 (2.251)	8.74 (1.782)	
95% CI [2]	-9.64, 12.51	2.83, 15.52	-1.12, 7.79	5.22, 12.27	
Difference (95% CI) in CFB [2]		7.74 (-4.21, 19.69)		5.41 (-0.05, 10.87)	
p-value [3]		0.197		0.052	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-pp-tryp-a.sas Date: 15:56/07AUG2023

Table 35.2.9.2.2.6a
Change from Baseline of EQ-5D-5L VAS by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	11	22	45	91	
Mean (StdDev)	56.8 (19.13)	57.6 (16.04)	54.2 (17.82)	64.3 (18.81)	
Median	60.0	60.0	56.0	66.0	
Min, Max	19, 90	25, 85	22, 91	10, 95	
C4D1 CFB					
n	9	22	44	89	
LS Mean (StdErr) [2]	0.61 (8.096)	8.81 (4.582)	2.33 (2.370)	8.87 (1.755)	
95% CI [2]	-15.97, 17.20	-0.57, 18.20	-2.36, 7.02	5.40, 12.34	
Difference (95% CI) in CFB [2]		8.20 (-9.09, 25.49)		6.54 (0.91, 12.17)	
p-value [3]		0.340		0.023	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-pp-tryp-a.sas Date: 15:56/07AUG2023

Table 35.2.9.2.2.6a
Change from Baseline of EQ-5D-5L VAS by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	25	48	84	
Mean (StdDev)	59.7 (20.38)	58.5 (17.20)	55.0 (18.17)	61.8 (19.10)	
Median	62.5	62.0	59.5	65.0	
Min, Max	16, 90	30, 85	10, 90	19, 93	
C5D1 CFB					
n	10	24	48	81	
LS Mean (StdErr) [2]	-2.47 (5.585)	4.84 (3.155)	1.38 (2.469)	5.57 (2.007)	
95% CI [2]	-13.86, 8.92	-1.59, 11.28	-3.51, 6.26	1.60, 9.54	
Difference (95% CI) in CFB [2]		7.31 (-4.67, 19.29)		4.19 (-1.88, 10.27)	
p-value [3]		0.223		0.175	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-pp-tryp-a.sas Date: 15:56/07AUG2023

Table 35.2.9.2.2.6a
Change from Baseline of EQ-5D-5L VAS by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	25	46	86	
Mean (StdDev)	61.3 (16.74)	59.5 (17.55)	51.6 (19.58)	63.3 (19.48)	
Median	61.0	60.0	50.0	67.5	
Min, Max	33, 91	25, 90	15, 96	13, 97	
C6D1 CFB					
n	10	24	46	83	
LS Mean (StdErr) [2]	-2.21 (5.481)	5.66 (3.096)	-0.59 (2.495)	7.29 (1.965)	
95% CI [2]	-13.38, 8.97	-0.66, 11.97	-5.53, 4.34	3.40, 11.17	
Difference (95% CI) in CFB [2]		7.86 (-3.90, 19.62)		7.88 (1.78, 13.98)	
p-value [3]		0.182		0.012	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-pp-tryp-a.sas Date: 15:56/07AUG2023

Table 35.2.9.2.2.6a
Change from Baseline of EQ-5D-5L VAS by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	11	24	47	87	
Mean (StdDev)	61.6 (18.22)	60.0 (16.37)	54.0 (20.33)	64.6 (19.56)	
Median	68.0	61.0	55.0	69.0	
Min, Max	28, 93	26, 90	16, 97	5, 95	
C7D1 CFB					
n	9	23	47	84	
LS Mean (StdErr) [2]	-0.72 (6.992)	6.65 (3.838)	0.93 (2.503)	8.81 (1.942)	
95% CI [2]	-15.02, 13.58	-1.20, 14.50	-4.02, 5.88	4.97, 12.65	
Difference (95% CI) in CFB [2]		7.38 (-7.74, 22.50)		7.88 (1.82, 13.94)	
Hedges'G (95% CI) in CFB		0.38 (-0.40, 1.21)		0.45 (0.09, 0.82)	
p-value [3]		0.327		0.011	
					0.905

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-pp-tryp-a.sas Date: 15:56/07AUG2023

Table 35.2.9.2.2.7a
Change from Baseline of EQ-5D-5L VAS by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	60	110	4	9	
Mean (StdDev)	57.7 (16.37)	55.9 (17.45)	24.5 (6.35)	51.8 (15.39)	
Median	60.0	55.0	24.5	49.0	
Min, Max	15, 94	15, 93	19, 30	32, 80	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-pp-ecog-a.sas Date: 15:56/07AUG2023

Table 35.2.9.2.2.7a
Change from Baseline of EQ-5D-5L VAS by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	60	111	4	8	
Mean (StdDev)	58.9 (15.92)	58.9 (17.98)	31.3 (15.17)	50.6 (18.61)	
Median	63.0	60.0	35.5	50.0	
Min, Max	15, 81	20, 90	10, 44	20, 71	
C2D1 CFB					
n	58	108	4	8	
LS Mean (StdErr) [2]	0.79 (2.035)	2.31 (1.596)	11.04 (9.130)	6.49 (7.199)	
95% CI [2]	-3.23, 4.81	-0.84, 5.46	-10.01, 32.10	-10.12, 23.09	
Difference (95% CI) in CFB [2]		1.52 (-2.87, 5.91)		-4.56 (-22.87, 13.76)	
p-value [3]		0.496		0.582	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-pp-ecog-a.sas Date: 15:56/07AUG2023

Table 35.2.9.2.2.7a
Change from Baseline of EQ-5D-5L VAS by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	59	102	4	8	
Mean (StdDev)	58.7 (18.66)	63.5 (18.02)	41.8 (24.20)	55.0 (15.32)	
Median	61.0	68.0	41.0	52.5	
Min, Max	12, 90	14, 96	15, 70	40, 74	
C3D1 CFB					
n	56	101	4	8	
LS Mean (StdErr) [2]	0.94 (2.289)	8.54 (1.767)	17.75 (14.598)	5.75 (11.509)	
95% CI [2]	-3.58, 5.47	5.05, 12.03	-15.91, 51.41	-20.79, 32.29	
Difference (95% CI) in CFB [2]		7.60 (2.66, 12.53)		-12.00 (-41.28, 17.28)	
p-value [3]		0.003		0.372	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
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Table 35.2.9.2.2.7a
Change from Baseline of EQ-5D-5L VAS by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	52	104	4	9	
Mean (StdDev)	56.2 (17.42)	63.9 (18.62)	34.8 (12.95)	53.2 (13.10)	
Median	60.0	65.5	29.5	55.0	
Min, Max	19, 91	10, 95	26, 54	30, 74	
C4D1 CFB					
n	49	102	4	9	
LS Mean (StdErr) [2]	0.08 (2.650)	8.55 (1.990)	12.20 (12.330)	6.60 (9.770)	
95% CI [2]	-5.16, 5.32	4.61, 12.48	-15.69, 40.09	-15.50, 28.70	
Difference (95% CI) in CFB [2]		8.46 (2.89, 14.04)		-5.60 (-29.66, 18.46)	
p-value [3]		0.003		0.611	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-pp-ecog-a.sas Date: 15:56/07AUG2023

Table 35.2.9.2.2.7a
Change from Baseline of EQ-5D-5L VAS by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	56	100	4	9	
Mean (StdDev)	57.6 (17.97)	62.0 (18.69)	32.8 (8.58)	51.3 (16.11)	
Median	60.0	65.0	30.5	50.0	
Min, Max	10, 90	19, 93	25, 45	21, 70	
C5D1 CFB					
n	54	96	4	9	
LS Mean (StdErr) [2]	-0.69 (2.558)	5.28 (1.990)	13.20 (10.884)	5.10 (8.625)	
95% CI [2]	-5.74, 4.37	1.34, 9.21	-11.42, 37.82	-14.41, 24.61	
Difference (95% CI) in CFB [2]		5.96 (0.43, 11.49)		-8.10 (-29.34, 13.14)	
p-value [3]		0.035		0.411	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-pp-ecog-a.sas Date: 15:56/07AUG2023

Table 35.2.9.2.2.7a
Change from Baseline of EQ-5D-5L VAS by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	102	4	9	
Mean (StdDev)	55.4 (18.69)	63.8 (18.69)	29.3 (7.27)	46.8 (16.72)	
Median	57.5	68.5	28.0	42.0	
Min, Max	15, 96	13, 97	22, 39	20, 70	
C6D1 CFB					
n	52	98	4	9	
LS Mean (StdErr) [2]	-1.71 (2.442)	7.39 (1.875)	8.40 (15.630)	2.20 (12.385)	
95% CI [2]	-6.53, 3.12	3.68, 11.09	-26.96, 43.76	-25.82, 30.22	
Difference (95% CI) in CFB [2]		9.10 (3.82, 14.38)		-6.20 (-36.70, 24.30)	
p-value [3]		<0.001		0.657	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-pp-ecog-a.sas Date: 15:56/07AUG2023

Table 35.2.9.2.2.7a
Change from Baseline of EQ-5D-5L VAS by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	54	102	4	9	
Mean (StdDev)	57.2 (19.61)	64.9 (18.93)	31.5 (1.29)	48.9 (11.94)	
Median	55.5	69.0	31.5	47.0	
Min, Max	16, 97	5, 95	30, 33	30, 63	
C7D1 CFB					
n	52	98	4	9	
LS Mean (StdErr) [2]	-0.81 (2.669)	8.44 (2.015)	10.83 (12.766)	3.73 (10.116)	
95% CI [2]	-6.08, 4.47	4.46, 12.43	-18.05, 39.70	-19.16, 26.61	
Difference (95% CI) in CFB [2]		9.25 (3.57, 14.93)		-7.10 (-32.01, 17.81)	
Hedges'G (95% CI) in CFB		0.47 (0.13, 0.82)		-0.23 (-1.61, 1.05)	
p-value [3]		0.002		0.535	
					0.083

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-pp-ecog-a.sas Date: 15:56/07AUG2023

Table 35.2.9.2.2.8a
Change from Baseline of EQ-5D-5L VAS by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	61	109	
Mean (StdDev)	68.3 (22.55)	46.2 (16.63)	55.0 (17.57)	56.5 (17.16)	
Median	70.0	40.5	59.0	57.0	
Min, Max	45, 90	26, 75	15, 94	15, 93	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-pp-thpy-a.sas Date: 15:56/07AUG2023

Table 35.2.9.2.2.8a
Change from Baseline of EQ-5D-5L VAS by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	61	109	
Mean (StdDev)	72.0 (7.55)	57.1 (16.07)	56.5 (17.18)	58.4 (18.30)	
Median	71.0	60.0	60.0	60.0	
Min, Max	65, 80	32, 83	10, 81	20, 90	
C2D1 CFB					
n	3	10	59	106	
LS Mean (StdErr) [2]	0.54 (11.731)	4.33 (10.376)	1.49 (1.957)	1.96 (1.540)	
95% CI [2]	-26.00, 27.07	-19.14, 27.80	-2.37, 5.36	-1.08, 5.00	
Difference (95% CI) in CFB [2]		3.80 (-26.53, 34.12)		0.47 (-3.73, 4.67)	
p-value [3]		0.783		0.825	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-pp-thpy-a.sas Date: 15:56/07AUG2023

Table 35.2.9.2.2.8a
Change from Baseline of EQ-5D-5L VAS by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	10	60	100	
Mean (StdDev)	74.0 (5.20)	58.3 (17.24)	56.8 (19.37)	63.3 (17.99)	
Median	71.0	60.5	60.5	68.0	
Min, Max	71, 80	30, 80	12, 90	14, 96	
C3D1 CFB					
n	3	10	57	99	
LS Mean (StdErr) [2]	1.54 (12.784)	3.33 (11.308)	2.05 (2.292)	8.24 (1.779)	
95% CI [2]	-27.38, 30.46	-22.25, 28.91	-2.48, 6.58	4.72, 11.75	
Difference (95% CI) in CFB [2]		1.80 (-31.26, 34.85)		6.19 (1.27, 11.11)	
p-value [3]		0.905		0.014	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
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Table 35.2.9.2.2.8a
Change from Baseline of EQ-5D-5L VAS by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	2	9	54	104	
Mean (StdDev)	59.0 (28.28)	62.8 (15.13)	54.5 (17.83)	63.0 (18.75)	
Median	59.0	65.0	58.0	64.5	
Min, Max	39, 79	37, 85	19, 91	10, 95	
C4D1 CFB					
n	2	9	51	102	
LS Mean (StdErr) [2]	6.41 (18.977)	15.20 (12.667)	1.05 (2.552)	7.45 (1.953)	
95% CI [2]	-38.47, 51.28	-14.76, 45.15	-4.00, 6.09	3.59, 11.31	
Difference (95% CI) in CFB [2]		8.79 (-38.46, 56.04)		6.41 (1.04, 11.78)	
p-value [3]		0.673		0.020	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
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Table 35.2.9.2.2.8a
Change from Baseline of EQ-5D-5L VAS by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	8	57	101	
Mean (StdDev)	70.0 (10.00)	63.5 (15.38)	55.2 (18.64)	60.9 (18.94)	
Median	70.0	64.5	59.0	65.0	
Min, Max	60, 80	32, 80	10, 90	19, 93	
C5D1 CFB					
n	3	8	55	97	
LS Mean (StdErr) [2]	-1.82 (12.523)	9.01 (11.059)	0.41 (2.509)	4.42 (1.954)	
95% CI [2]	-31.43, 27.79	-17.14, 35.16	-4.54, 5.37	0.55, 8.28	
Difference (95% CI) in CFB [2]		10.83 (-23.20, 44.87)		4.00 (-1.37, 9.37)	
p-value [3]		0.476		0.143	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
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Table 35.2.9.2.2.8a
Change from Baseline of EQ-5D-5L VAS by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	55	102	
Mean (StdDev)	65.0 (18.03)	61.3 (20.37)	53.0 (19.32)	62.5 (19.03)	
Median	70.0	68.0	52.0	66.0	
Min, Max	45, 80	24, 90	15, 96	13, 97	
C6D1 CFB					
n	3	9	53	98	
LS Mean (StdErr) [2]	-5.48 (16.297)	10.06 (14.405)	-0.36 (2.433)	6.32 (1.872)	
95% CI [2]	-43.06, 32.10	-23.16, 43.28	-5.17, 4.44	2.62, 10.02	
Difference (95% CI) in CFB [2]		15.54 (-27.51, 58.60)		6.69 (1.47, 11.90)	
p-value [3]		0.429		0.012	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
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Table 35.2.9.2.2.8a
Change from Baseline of EQ-5D-5L VAS by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	8	55	103	
Mean (StdDev)	65.3 (14.19)	68.3 (12.14)	54.9 (20.25)	63.2 (19.36)	
Median	68.0	67.5	55.0	67.0	
Min, Max	50, 78	50, 90	16, 97	5, 95	
C7D1 CFB					
n	3	8	53	99	
LS Mean (StdErr) [2]	-5.72 (14.728)	13.37 (13.006)	0.57 (2.626)	7.14 (1.988)	
95% CI [2]	-40.54, 29.11	-17.39, 44.12	-4.62, 5.76	3.22, 11.07	
Difference (95% CI) in CFB [2]		19.08 (-20.95, 59.11)		6.58 (1.05, 12.10)	
Hedges'G (95% CI) in CFB		0.50 (-0.91, 2.21)		0.33 (0.00, 0.68)	
p-value [3]		0.297		0.020	
					0.184

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-pp-thpy-a.sas Date: 15:56/07AUG2023

Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

Table 35.2.9.4.2a
Proportion of Patients with >=15 Points Increase in EQ-5D-5L VAS at C7D1
Per Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1 with EQ-5D-5L VAS at Baseline, Part 2 (Part 2 Baseline)

Patients with >= 15 Points Increase at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Overall	6/ 67 (9.0) (3.4, 18.5)	37/123 (30.1) (22.1, 39.0)	4.44 (1.73, 13.91) <0.001	3.42 (1.53, 7.63) 0.003	0.22 (0.11, 0.33) <0.0001	
Age Group (Years)						0.973
< 65	6/ 56 (10.7) (4.0, 21.9)	32/117 (27.4) (19.5, 36.4)	3.19 (1.19, 9.91) 0.013	2.60 (1.15, 5.89) 0.022	0.17 (0.05, 0.29) 0.004	
>= 65	0/ 11 (0.0) (0.0, 28.5)	5/ 6 (83.3) (35.9, 99.6)	NE (2.27, NE) 0.003	NE (NE, NE) NE	0.86 (0.62, 1.00) <0.0001	
Sex						0.750
Male	2/ 15 (13.3) (1.7, 40.5)	12/ 35 (34.3) (19.1, 52.2)	3.45 (0.57, 34.94) 0.145	2.54 (0.64, 10.16) 0.187	0.20 (-0.03, 0.43) 0.084	
Female	4/ 52 (7.7) (2.1, 18.5)	25/ 88 (28.4) (19.3, 39.0)	4.80 (1.64, 22.35) 0.002	3.81 (1.45, 10.00) 0.007	0.23 (0.10, 0.35) <0.001	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.9.4.2a
Proportion of Patients with >=15 Points Increase in EQ-5D-5L VAS at C7D1
Per Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1 with EQ-5D-5L VAS at Baseline, Part 2 (Part 2 Baseline)

Patients with >= 15 Points Increase at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Region						0.466
North America	2/ 32 (6.3) (0.8, 20.8)	16/ 52 (30.8) (18.7, 45.1)	7.56 (1.52, 71.73) 0.005	5.59 (1.32, 23.70) 0.019	0.28 (0.12, 0.44) <0.001	
Europe	4/ 35 (11.4) (3.2, 26.7)	21/ 71 (29.6) (19.3, 41.6)	3.18 (0.94, 13.72) 0.043	2.57 (0.95, 6.98) 0.064	0.18 (0.03, 0.33) 0.020	
Country						>0.999
BEL	0/ 1 (0.0) (0.0, 97.5)	0/ 2 (0.0) (0.0, 84.2)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
CAN	0/ 5 (0.0) (0.0, 52.2)	1/ 8 (12.5) (0.3, 52.7)	NE (0.01, NE) 0.655	NE (NE, NE) NE	0.08 (-0.18, 0.34) 0.540	
CHE	0/ 1 (0.0) (0.0, 97.5)	0/ 2 (0.0) (0.0, 84.2)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
DEU	2/ 14 (14.3) (1.8, 42.8)	5/ 17 (29.4) (10.3, 56.0)	1.97 (0.25, 26.21) 0.414	1.78 (0.40, 7.87) 0.449	0.12 (-0.18, 0.42) 0.428	
DNK	0/0	1/ 1 (100.0) (2.5, 100.0)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.9.4.2a
Proportion of Patients with >=15 Points Increase in EQ-5D-5L VAS at C7D1
Per Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1 with EQ-5D-5L VAS at Baseline, Part 2 (Part 2 Baseline)

Patients with >= 15 Points Increase at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
ESP	0/ 3 (0.0) (0.0, 70.8)	3/ 13 (23.1) (5.0, 53.8)	NE (0.17, NE) 0.294	NE (NE, NE) NE	0.31 (0.03, 0.59) 0.030	
FRA	1/ 5 (20.0) (0.5, 71.6)	4/ 10 (40.0) (12.2, 73.8)	4.00 (0.16, 215.82) 0.382	2.50 (0.27, 23.36) 0.422	0.25 (-0.20, 0.70) 0.281	
GBR	0/ 5 (0.0) (0.0, 52.2)	3/ 10 (30.0) (6.7, 65.2)	NE (0.05, NE) 0.317	NE (NE, NE) NE	0.17 (-0.11, 0.45) 0.234	
ITA	0/0	0/ 3 (0.0) (0.0, 70.8)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
NLD	0/ 3 (0.0) (0.0, 70.8)	2/ 7 (28.6) (3.7, 71.0)	NE (0.05, NE) 0.317	NE (NE, NE) NE	0.33 (-0.20, 0.87) 0.221	
NOR	1/ 2 (50.0) (1.3, 98.7)	3/ 5 (60.0) (14.7, 94.7)	1.50 (0.02, 117.66) 0.808	1.25 (0.20, 7.82) 0.811	0.12 (-0.76, 1.00) 0.794	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.9.4.2a
Proportion of Patients with >=15 Points Increase in EQ-5D-5L VAS at C7D1
Per Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1 with EQ-5D-5L VAS at Baseline, Part 2 (Part 2 Baseline)

Patients with >= 15 Points Increase at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
SWE	0/ 1 (0.0) (0.0, 97.5)	0/ 1 (0.0) (0.0, 97.5)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
USA	2/ 27 (7.4) (0.9, 24.3)	15/ 44 (34.1) (20.5, 49.9)	7.88 (1.45, 71.47) 0.006	5.49 (1.26, 23.92) 0.023	0.30 (0.13, 0.48) <0.001	
Baseline ISM Status						0.245
Moderate	1/ 22 (4.5) (0.1, 22.8)	13/ 37 (35.1) (20.2, 52.5)	14.04 (1.62, 608.71) 0.005	8.73 (1.19, 64.02) 0.033	0.34 (0.15, 0.52) <0.001	
Severe	5/ 45 (11.1) (3.7, 24.1)	24/ 86 (27.9) (18.8, 38.6)	3.06 (1.02, 10.94) 0.031	2.49 (1.02, 6.07) 0.046	0.17 (0.03, 0.30) 0.014	
Baseline Serum Tryptase (ng/mL)						0.812
< 20	1/ 13 (7.7) (0.2, 36.0)	6/ 26 (23.1) (9.0, 43.6)	4.08 (0.36, 197.89) 0.225	3.31 (0.41, 27.08) 0.264	0.17 (-0.06, 0.39) 0.143	
>= 20	5/ 54 (9.3) (3.1, 20.3)	31/ 97 (32.0) (22.9, 42.2)	4.51 (1.63, 16.50) 0.002	3.43 (1.44, 8.19) 0.005	0.23 (0.11, 0.35) <0.001	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.9.4.2a
Proportion of Patients with >=15 Points Increase in EQ-5D-5L VAS at C7D1
Per Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1 with EQ-5D-5L VAS at Baseline, Part 2 (Part 2 Baseline)

Patients with >= 15 Points Increase at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
ECOG Status						0.982
0 or 1	6/ 63 (9.5) (3.6, 19.6)	36/114 (31.6) (23.2, 40.9)	4.48 (1.70, 13.84) <0.001	3.37 (1.51, 7.52) 0.003	0.23 (0.11, 0.34) <0.0001	
2+	0/ 4 (0.0) (0.0, 60.2)	1/ 9 (11.1) (0.3, 48.2)	NE (0.05, NE) 0.317	NE (NE, NE) NE	0.20 (-0.08, 0.48) 0.157	
Prior TKI therapy						0.971
Yes	0/ 3 (0.0) (0.0, 70.8)	6/ 10 (60.0) (26.2, 87.8)	NE (0.41, NE) 0.090	NE (NE, NE) NE	0.57 (0.18, 0.97) 0.005	
No	6/ 64 (9.4) (3.5, 19.3)	31/113 (27.4) (19.5, 36.6)	3.70 (1.42, 11.94) 0.004	2.99 (1.32, 6.77) 0.009	0.19 (0.08, 0.30) <0.001	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.7.2.2a
Summary of PGIC by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	13	33	50	86	
Mean (StdDev)	3.0 (1.68)	3.1 (1.42)	2.5 (1.42)	3.3 (1.74)	
Median	2.0	3.0	2.0	3.0	
Min, Max	1, 5	1, 6	1, 6	1, 7	
LS Mean (StdErr) [2]	3.30 (0.450)	3.28 (0.286)	2.42 (0.264)	3.23 (0.225)	
95% CI [2]	2.39, 4.20	2.70, 3.86	1.90, 2.94	2.79, 3.68	
Difference (95% CI) [2]		-0.01 (-1.00, 0.98)		0.81 (0.24, 1.39)	
p-value [3]		0.979		0.006	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-pp-sex-a.sas Date: 15:50/07AUG2023

Table 35.2.7.2.2a
Summary of PGIC by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	28	47	82	
Mean (StdDev)	2.9 (1.83)	3.8 (1.72)	2.9 (1.57)	4.0 (1.74)	
Median	2.0	4.0	2.0	4.0	
Min, Max	1, 6	1, 7	1, 7	1, 7	
LS Mean (StdErr) [2]	2.73 (0.498)	3.65 (0.372)	2.85 (0.282)	3.96 (0.232)	
95% CI [2]	1.72, 3.74	2.90, 4.40	2.29, 3.41	3.50, 4.42	
Difference (95% CI) [2]		0.92 (-0.23, 2.07)		1.11 (0.50, 1.72)	
p-value [3]		0.114		<0.001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-pp-sex-a.sas Date: 15:50/07AUG2023

Table 35.2.7.2.2a
Summary of PGIC by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	13	30	43	82	
Mean (StdDev)	2.7 (1.49)	3.9 (1.64)	2.7 (1.81)	4.2 (1.73)	
Median	2.0	4.0	2.0	5.0	
Min, Max	1, 5	1, 6	1, 7	1, 7	
LS Mean (StdErr) [2]	2.65 (0.474)	3.87 (0.345)	2.49 (0.308)	3.99 (0.248)	
95% CI [2]	1.69, 3.61	3.17, 4.57	1.88, 3.10	3.50, 4.48	
Difference (95% CI) [2]		1.22 (0.14, 2.29)		1.50 (0.84, 2.15)	
p-value [3]		0.027		<0.0001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
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Table 35.2.7.2.2a
Summary of PGIC by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	31	45	77	
Mean (StdDev)	2.9 (1.85)	4.4 (1.50)	2.5 (1.65)	4.2 (1.84)	
Median	2.0	5.0	2.0	5.0	
Min, Max	1, 6	1, 6	1, 6	1, 7	
LS Mean (StdErr) [2]	2.69 (0.454)	4.21 (0.323)	2.48 (0.303)	4.18 (0.251)	
95% CI [2]	1.77, 3.61	3.56, 4.86	1.88, 3.08	3.68, 4.67	
Difference (95% CI) [2]		1.52 (0.49, 2.56)		1.69 (1.03, 2.36)	
p-value [3]		0.005		<0.0001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-pp-sex-a.sas Date: 15:50/07AUG2023

Table 35.2.7.2.2a
Summary of PGIC by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	13	32	45	78	
Mean (StdDev)	2.5 (1.56)	4.3 (1.74)	2.6 (1.71)	4.3 (1.88)	
Median	2.0	5.0	2.0	5.0	
Min, Max	1, 5	1, 7	1, 7	1, 7	
LS Mean (StdErr) [2]	2.55 (0.508)	4.25 (0.342)	2.47 (0.306)	4.18 (0.254)	
95% CI [2]	1.52, 3.57	3.56, 4.94	1.86, 3.08	3.68, 4.69	
Difference (95% CI) [2]		1.71 (0.56, 2.85)		1.71 (1.04, 2.39)	
p-value [3]		0.005		<0.0001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-pp-sex-a.sas Date: 15:50/07AUG2023

Table 35.2.7.2.2a
Summary of PGIC by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	14	34	44	77	
Mean (StdDev)	3.2 (1.97)	4.1 (1.56)	2.6 (1.83)	4.3 (1.79)	
Median	3.0	4.5	2.0	5.0	
Min, Max	1, 6	1, 6	1, 7	1, 7	
LS Mean (StdErr) [2]	3.14 (0.491)	4.02 (0.326)	2.58 (0.316)	4.29 (0.260)	
95% CI [2]	2.15, 4.13	3.37, 4.68	1.95, 3.20	3.78, 4.80	
Difference (95% CI) [2]		0.89 (-0.22, 1.99)		1.71 (1.03, 2.39)	
Hedges'G (95% CI)		0.46 (-0.16, 1.13)		0.77 (0.39, 1.17)	
p-value [3]		0.113		<0.0001	
					0.210

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-pp-sex-a.sas Date: 15:50/07AUG2023

Table 35.2.7.2.2a
Summary of PGIC by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Degree of Change	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	13	33	50	86	
Mean (StdDev)	4.0 (1.53)	4.1 (1.41)	4.6 (1.03)	4.4 (1.62)	
Median	4.0	4.0	5.0	5.0	
Min, Max	0, 6	1, 6	1, 8	0, 8	
LS Mean (StdErr) [2]	4.05 (0.448)	4.09 (0.285)	4.63 (0.233)	4.43 (0.198)	
95% CI [2]	3.15, 4.96	3.52, 4.67	4.17, 5.09	4.04, 4.82	
Difference (95% CI) [2]		0.04 (-0.94, 1.02)		-0.20 (-0.70, 0.31)	
p-value [3]		0.936		0.445	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-pp-sex-a.sas Date: 15:50/07AUG2023

Table 35.2.7.2.2a
Summary of PGIC by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Degree of Change	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	28	47	81	
Mean (StdDev)	4.3 (1.75)	3.5 (1.32)	4.5 (1.25)	3.7 (1.73)	
Median	5.0	3.0	5.0	4.0	
Min, Max	1, 7	1, 6	1, 7	0, 9	
LS Mean (StdErr) [2]	4.46 (0.416)	3.70 (0.311)	4.45 (0.264)	3.69 (0.218)	
95% CI [2]	3.62, 5.30	3.07, 4.33	3.93, 4.97	3.26, 4.12	
Difference (95% CI) [2]		-0.76 (-1.72, 0.20)		-0.76 (-1.34, -0.19)	
p-value [3]		0.117		0.009	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-pp-sex-a.sas Date: 15:50/07AUG2023

Table 35.2.7.2.2a
Summary of PGIC by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Degree of Change	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	13	30	43	82	
Mean (StdDev)	4.4 (1.61)	3.4 (1.33)	4.8 (1.65)	3.9 (1.67)	
Median	5.0	3.0	5.0	4.0	
Min, Max	1, 7	1, 7	1, 8	0, 9	
LS Mean (StdErr) [2]	4.27 (0.406)	3.30 (0.296)	4.94 (0.293)	4.03 (0.236)	
95% CI [2]	3.45, 5.09	2.70, 3.90	4.36, 5.52	3.56, 4.49	
Difference (95% CI) [2]		-0.97 (-1.89, -0.05)		-0.92 (-1.54, -0.30)	
p-value [3]		0.039		0.004	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-pp-sex-a.sas Date: 15:50/07AUG2023

Table 35.2.7.2.2a
Summary of PGIC by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Degree of Change	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	31	45	77	
Mean (StdDev)	4.7 (1.80)	3.7 (1.40)	4.8 (1.34)	3.7 (1.82)	
Median	5.0	4.0	5.0	3.0	
Min, Max	2, 9	1, 7	2, 7	0, 9	
LS Mean (StdErr) [2]	4.99 (0.380)	3.97 (0.271)	4.85 (0.282)	3.73 (0.234)	
95% CI [2]	4.22, 5.76	3.43, 4.52	4.29, 5.41	3.27, 4.19	
Difference (95% CI) [2]		-1.02 (-1.89, -0.15)		-1.12 (-1.74, -0.50)	
p-value [3]		0.022		<0.001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-pp-sex-a.sas Date: 15:50/07AUG2023

Table 35.2.7.2.2a
Summary of PGIC by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Degree of Change	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	13	32	45	78	
Mean (StdDev)	4.9 (1.71)	4.0 (1.64)	4.8 (1.60)	3.7 (1.90)	
Median	5.0	4.0	5.0	4.0	
Min, Max	3, 8	1, 8	0, 7	0, 9	
LS Mean (StdErr) [2]	4.82 (0.491)	3.88 (0.331)	4.83 (0.305)	3.77 (0.253)	
95% CI [2]	3.83, 5.81	3.21, 4.55	4.22, 5.43	3.27, 4.27	
Difference (95% CI) [2]		-0.94 (-2.05, 0.17)		-1.05 (-1.73, -0.38)	
p-value [3]		0.095		0.002	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-pp-sex-a.sas Date: 15:50/07AUG2023

Table 35.2.7.2.2a
Summary of PGIC by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Degree of Change	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	14	34	44	77	
Mean (StdDev)	4.9 (1.41)	3.9 (1.46)	4.9 (1.65)	3.6 (2.01)	
Median	5.0	4.0	5.0	3.0	
Min, Max	3, 7	0, 7	1, 8	0, 9	
LS Mean (StdErr) [2]	4.74 (0.408)	3.78 (0.271)	4.93 (0.331)	3.61 (0.273)	
95% CI [2]	3.92, 5.57	3.23, 4.33	4.27, 5.58	3.07, 4.15	
Difference (95% CI) [2]		-0.96 (-1.88, -0.05)		-1.32 (-2.03, -0.61)	
Hedges'G (95% CI)		-0.61 (-1.29, 0.02)		-0.56 (-0.96, -0.19)	
p-value [3]		0.040		<0.001	
					0.615

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-pp-sex-a.sas Date: 15:50/07AUG2023

Table 35.2.7.2.3a
Summary of PGIC by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	28	51	35	68	
Mean (StdDev)	2.5 (1.53)	3.2 (1.64)	2.7 (1.45)	3.3 (1.68)	
Median	2.0	3.0	2.0	3.0	
Min, Max	1, 6	1, 7	1, 5	1, 7	
LS Mean (StdErr) [2]	2.69 (0.338)	3.41 (0.272)	2.57 (0.305)	3.16 (0.236)	
95% CI [2]	2.01, 3.36	2.87, 3.96	1.97, 3.18	2.69, 3.62	
Difference (95% CI) [2]		0.73 (-0.02, 1.47)		0.58 (-0.08, 1.25)	
p-value [3]		0.056		0.084	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-pp-reg-a.sas Date: 15:50/07AUG2023

Table 35.2.7.2.3a
Summary of PGIC by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	28	44	34	66	
Mean (StdDev)	2.7 (1.68)	4.1 (1.58)	3.1 (1.56)	3.9 (1.84)	
Median	2.0	5.0	3.0	4.0	
Min, Max	1, 7	1, 6	1, 6	1, 7	
LS Mean (StdErr) [2]	2.55 (0.343)	3.93 (0.297)	3.07 (0.336)	3.87 (0.253)	
95% CI [2]	1.86, 3.23	3.33, 4.52	2.40, 3.73	3.37, 4.37	
Difference (95% CI) [2]		1.38 (0.60, 2.16)		0.80 (0.07, 1.53)	
p-value [3]		<0.001		0.032	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-pp-reg-a.sas Date: 15:50/07AUG2023

Table 35.2.7.2.3a
Summary of PGIC by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	22	43	34	69	
Mean (StdDev)	2.8 (1.89)	4.2 (1.53)	2.7 (1.65)	4.1 (1.82)	
Median	2.0	5.0	2.0	5.0	
Min, Max	1, 7	1, 6	1, 6	1, 7	
LS Mean (StdErr) [2]	2.67 (0.403)	4.00 (0.338)	2.54 (0.337)	4.02 (0.252)	
95% CI [2]	1.87, 3.48	3.32, 4.67	1.87, 3.21	3.52, 4.52	
Difference (95% CI) [2]		1.32 (0.45, 2.20)		1.48 (0.75, 2.21)	
p-value [3]		0.004		<0.001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-pp-reg-a.sas Date: 15:50/07AUG2023

Table 35.2.7.2.3a
Summary of PGIC by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	26	40	34	68	
Mean (StdDev)	2.6 (1.77)	4.3 (1.66)	2.6 (1.65)	4.2 (1.80)	
Median	2.0	5.0	2.0	5.0	
Min, Max	1, 6	1, 6	1, 6	1, 7	
LS Mean (StdErr) [2]	2.78 (0.375)	4.40 (0.317)	2.40 (0.335)	4.06 (0.252)	
95% CI [2]	2.03, 3.52	3.77, 5.03	1.73, 3.06	3.56, 4.56	
Difference (95% CI) [2]		1.63 (0.76, 2.49)		1.66 (0.94, 2.39)	
p-value [3]		<0.001		<0.0001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-pp-reg-a.sas Date: 15:50/07AUG2023

Table 35.2.7.2.3a
Summary of PGIC by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	24	43	34	67	
Mean (StdDev)	2.8 (1.98)	4.5 (1.65)	2.4 (1.42)	4.1 (1.93)	
Median	2.0	5.0	2.0	4.0	
Min, Max	1, 7	1, 7	1, 6	1, 7	
LS Mean (StdErr) [2]	2.97 (0.398)	4.74 (0.328)	2.17 (0.335)	3.87 (0.251)	
95% CI [2]	2.18, 3.77	4.09, 5.40	1.50, 2.83	3.37, 4.37	
Difference (95% CI) [2]		1.77 (0.85, 2.68)		1.70 (0.97, 2.43)	
p-value [3]		<0.001		<0.0001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-pp-reg-a.sas Date: 15:50/07AUG2023

Table 35.2.7.2.3a
Summary of PGIC by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	24	44	34	67	
Mean (StdDev)	3.0 (2.14)	4.6 (1.45)	2.6 (1.67)	4.0 (1.85)	
Median	2.0	5.0	2.0	4.0	
Min, Max	1, 7	1, 6	1, 6	1, 7	
LS Mean (StdErr) [2]	3.17 (0.399)	4.83 (0.319)	2.40 (0.343)	3.81 (0.257)	
95% CI [2]	2.37, 3.97	4.19, 5.47	1.72, 3.08	3.30, 4.32	
Difference (95% CI) [2]		1.66 (0.79, 2.54)		1.41 (0.67, 2.16)	
Hedges'G (95% CI)		0.80 (0.30, 1.35)		0.68 (0.26, 1.12)	
p-value [3]		<0.001		<0.001	
					0.635

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-pp-reg-a.sas Date: 15:50/07AUG2023

Table 35.2.7.2.3a
Summary of PGIC by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Degree of Change	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	28	51	35	68	
Mean (StdDev)	4.2 (1.33)	4.3 (1.38)	4.7 (0.96)	4.3 (1.70)	
Median	4.5	5.0	5.0	4.0	
Min, Max	0, 6	1, 8	3, 8	0, 8	
LS Mean (StdErr) [2]	4.15 (0.294)	4.31 (0.237)	4.75 (0.286)	4.32 (0.221)	
95% CI [2]	3.57, 4.74	3.84, 4.78	4.19, 5.32	3.88, 4.76	
Difference (95% CI) [2]		0.16 (-0.49, 0.81)		-0.44 (-1.06, 0.19)	
p-value [3]		0.626		0.167	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
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Table 35.2.7.2.3a
Summary of PGIC by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Degree of Change	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	28	43	34	66	
Mean (StdDev)	4.4 (1.47)	3.7 (1.30)	4.4 (1.31)	3.7 (1.82)	
Median	5.0	4.0	5.0	4.0	
Min, Max	1, 7	1, 7	1, 6	0, 9	
LS Mean (StdErr) [2]	4.36 (0.295)	3.64 (0.257)	4.51 (0.323)	3.71 (0.243)	
95% CI [2]	3.77, 4.95	3.13, 4.15	3.87, 5.15	3.23, 4.19	
Difference (95% CI) [2]		-0.72 (-1.40, -0.04)		-0.80 (-1.50, -0.09)	
p-value [3]		0.037		0.027	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
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Table 35.2.7.2.3a
Summary of PGIC by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Degree of Change	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	22	43	34	69	
Mean (StdDev)	4.5 (1.82)	3.8 (1.28)	4.9 (1.52)	3.7 (1.77)	
Median	5.0	4.0	5.0	4.0	
Min, Max	1, 7	1, 8	2, 8	0, 9	
LS Mean (StdErr) [2]	4.43 (0.360)	3.73 (0.302)	4.85 (0.325)	3.74 (0.243)	
95% CI [2]	3.71, 5.15	3.12, 4.33	4.21, 5.50	3.26, 4.23	
Difference (95% CI) [2]		-0.70 (-1.48, 0.08)		-1.11 (-1.82, -0.41)	
p-value [3]		0.077		0.002	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
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Table 35.2.7.2.3a
Summary of PGIC by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Degree of Change	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	26	40	34	68	
Mean (StdDev)	4.7 (1.55)	3.7 (1.44)	4.9 (1.40)	3.7 (1.85)	
Median	5.0	3.0	5.0	4.0	
Min, Max	2, 7	2, 7	2, 9	0, 9	
LS Mean (StdErr) [2]	4.58 (0.327)	3.54 (0.276)	5.09 (0.328)	3.90 (0.247)	
95% CI [2]	3.92, 5.23	2.99, 4.10	4.43, 5.74	3.41, 4.39	
Difference (95% CI) [2]		-1.03 (-1.79, -0.28)		-1.18 (-1.90, -0.47)	
p-value [3]		0.008		0.001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.7.2.3a
Summary of PGIC by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Degree of Change	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	24	43	34	67	
Mean (StdDev)	4.4 (1.89)	4.0 (1.81)	5.1 (1.34)	3.6 (1.83)	
Median	5.0	4.0	5.0	3.0	
Min, Max	0, 8	1, 8	2, 8	0, 9	
LS Mean (StdErr) [2]	4.17 (0.405)	3.85 (0.333)	5.25 (0.326)	3.76 (0.244)	
95% CI [2]	3.36, 4.98	3.18, 4.52	4.60, 5.89	3.27, 4.24	
Difference (95% CI) [2]		-0.32 (-1.25, 0.61)		-1.49 (-2.20, -0.78)	
p-value [3]		0.494		<0.0001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.7.2.3a
Summary of PGIC by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Degree of Change	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	24	44	34	67	
Mean (StdDev)	4.6 (1.71)	3.7 (1.65)	5.1 (1.48)	3.6 (1.99)	
Median	5.0	3.0	5.0	4.0	
Min, Max	1, 8	1, 8	2, 8	0, 9	
LS Mean (StdErr) [2]	4.36 (0.386)	3.47 (0.309)	5.20 (0.356)	3.73 (0.267)	
95% CI [2]	3.59, 5.13	2.85, 4.08	4.49, 5.91	3.20, 4.25	
Difference (95% CI) [2]		-0.89 (-1.74, -0.05)		-1.47 (-2.25, -0.70)	
Hedges'G (95% CI)		-0.44 (-0.97, 0.05)		-0.68 (-1.13, -0.27)	
p-value [3]		0.039		<0.001	
					0.346

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.7.2.4a
Summary of PGIC by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.7.2.4a
Summary of PGIC by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change						
	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
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Table 35.2.7.2.4a
Summary of PGIC by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
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Table 35.2.7.2.4a
Summary of PGIC by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
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Table 35.2.7.2.4a
Summary of PGIC by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change			
	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
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Table 35.2.7.2.4a
Summary of PGIC by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Degree of Change	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
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Table 35.2.7.2.4a
Summary of PGIC by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Degree of Change	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
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Table 35.2.7.2.4a
Summary of PGIC by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Degree of Change	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
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Table 35.2.7.2.4a
Summary of PGIC by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Degree of Change	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
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Table 35.2.7.2.4a
Summary of PGIC by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Degree of Change	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-pp-cou-a.sas Date: 15:50/07AUG2023

Table 35.2.7.2.5a
Summary of PGIC by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	20	35	43	84	
Mean (StdDev)	2.2 (1.23)	3.3 (1.62)	2.8 (1.55)	3.3 (1.68)	
Median	2.0	3.0	2.0	3.0	
Min, Max	1, 5	1, 6	1, 6	1, 7	
LS Mean (StdErr) [2]	2.09 (0.412)	3.26 (0.278)	2.87 (0.265)	3.32 (0.213)	
95% CI [2]	1.27, 2.92	2.70, 3.82	2.34, 3.39	2.89, 3.74	
Difference (95% CI) [2]		1.17 (0.28, 2.05)		0.45 (-0.16, 1.06)	
p-value [3]		0.011		0.145	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-pp-ism-a.sas Date: 15:50/07AUG2023

Table 35.2.7.2.5a
Summary of PGIC by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	18	33	44	77	
Mean (StdDev)	2.7 (1.64)	4.2 (1.73)	3.0 (1.61)	3.9 (1.74)	
Median	2.0	5.0	2.0	4.0	
Min, Max	1, 6	1, 7	1, 7	1, 7	
LS Mean (StdErr) [2]	2.35 (0.458)	3.97 (0.323)	2.97 (0.272)	3.83 (0.225)	
95% CI [2]	1.43, 3.28	3.32, 4.62	2.43, 3.51	3.38, 4.27	
Difference (95% CI) [2]		1.61 (0.60, 2.63)		0.86 (0.22, 1.50)	
p-value [3]		0.002		0.009	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-pp-ism-a.sas Date: 15:50/07AUG2023

Table 35.2.7.2.5a
Summary of PGIC by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	17	33	39	79	
Mean (StdDev)	2.3 (1.57)	4.3 (1.53)	2.9 (1.78)	4.1 (1.78)	
Median	2.0	5.0	2.0	4.0	
Min, Max	1, 6	2, 6	1, 7	1, 7	
LS Mean (StdErr) [2]	2.04 (0.433)	4.14 (0.315)	2.79 (0.305)	3.93 (0.236)	
95% CI [2]	1.17, 2.91	3.51, 4.77	2.18, 3.39	3.46, 4.40	
Difference (95% CI) [2]		2.10 (1.17, 3.03)		1.14 (0.46, 1.83)	
p-value [3]		<0.0001		0.001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-pp-ism-a.sas Date: 15:50/07AUG2023

Table 35.2.7.2.5a
Summary of PGIC by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	32	41	76	
Mean (StdDev)	2.3 (1.57)	4.5 (1.52)	2.7 (1.75)	4.1 (1.83)	
Median	2.0	5.0	2.0	5.0	
Min, Max	1, 6	1, 6	1, 6	1, 7	
LS Mean (StdErr) [2]	2.26 (0.416)	4.47 (0.299)	2.63 (0.300)	4.03 (0.237)	
95% CI [2]	1.43, 3.10	3.87, 5.07	2.04, 3.23	3.56, 4.50	
Difference (95% CI) [2]		2.21 (1.28, 3.13)		1.40 (0.71, 2.09)	
p-value [3]		<0.0001		<0.001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-pp-ism-a.sas Date: 15:50/07AUG2023

Table 35.2.7.2.5a
Summary of PGIC by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	19	33	39	77	
Mean (StdDev)	2.4 (1.46)	4.7 (1.69)	2.7 (1.77)	4.1 (1.87)	
Median	2.0	5.0	2.0	4.0	
Min, Max	1, 6	1, 7	1, 7	1, 7	
LS Mean (StdErr) [2]	2.29 (0.434)	4.62 (0.310)	2.53 (0.310)	3.93 (0.240)	
95% CI [2]	1.41, 3.16	4.00, 5.24	1.92, 3.15	3.45, 4.41	
Difference (95% CI) [2]		2.33 (1.37, 3.29)		1.40 (0.68, 2.11)	
p-value [3]		<0.0001		<0.001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
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Table 35.2.7.2.5a
Summary of PGIC by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	18	35	40	76	
Mean (StdDev)	2.7 (1.74)	4.4 (1.44)	2.8 (1.94)	4.2 (1.84)	
Median	2.5	5.0	2.0	5.0	
Min, Max	1, 6	1, 6	1, 7	1, 7	
LS Mean (StdErr) [2]	2.62 (0.422)	4.36 (0.294)	2.70 (0.319)	4.07 (0.251)	
95% CI [2]	1.77, 3.47	3.77, 4.95	2.07, 3.33	3.58, 4.57	
Difference (95% CI) [2]		1.75 (0.82, 2.67)		1.37 (0.65, 2.10)	
Hedges'G (95% CI)		0.98 (0.41, 1.64)		0.64 (0.26, 1.05)	
p-value [3]		<0.001		<0.001	
					0.543

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.7.2.5a
Summary of PGIC by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Degree of Change	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	20	35	43	84	
Mean (StdDev)	4.6 (1.47)	4.3 (1.30)	4.4 (1.00)	4.3 (1.67)	
Median	5.0	5.0	5.0	4.0	
Min, Max	0, 8	2, 7	1, 6	0, 8	
LS Mean (StdErr) [2]	4.88 (0.371)	4.47 (0.251)	4.34 (0.240)	4.19 (0.193)	
95% CI [2]	4.13, 5.62	3.97, 4.98	3.87, 4.82	3.81, 4.58	
Difference (95% CI) [2]		-0.40 (-1.20, 0.39)		-0.15 (-0.70, 0.40)	
p-value [3]		0.315		0.594	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
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Table 35.2.7.2.5a
Summary of PGIC by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Degree of Change	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	18	33	44	76	
Mean (StdDev)	4.3 (1.53)	3.6 (1.34)	4.5 (1.32)	3.7 (1.75)	
Median	5.0	4.0	5.0	4.0	
Min, Max	1, 6	1, 8	1, 7	0, 9	
LS Mean (StdErr) [2]	4.46 (0.386)	3.71 (0.271)	4.47 (0.259)	3.68 (0.214)	
95% CI [2]	3.68, 5.23	3.16, 4.25	3.95, 4.98	3.26, 4.11	
Difference (95% CI) [2]		-0.75 (-1.60, 0.10)		-0.78 (-1.39, -0.18)	
p-value [3]		0.084		0.012	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
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Table 35.2.7.2.5a
Summary of PGIC by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Degree of Change	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	17	33	39	79	
Mean (StdDev)	4.4 (1.27)	3.8 (1.51)	4.9 (1.76)	3.7 (1.64)	
Median	5.0	4.0	5.0	4.0	
Min, Max	1, 6	1, 8	1, 8	0, 9	
LS Mean (StdErr) [2]	4.33 (0.407)	3.80 (0.296)	4.90 (0.290)	3.77 (0.225)	
95% CI [2]	3.51, 5.15	3.21, 4.40	4.33, 5.48	3.32, 4.21	
Difference (95% CI) [2]		-0.53 (-1.41, 0.35)		-1.13 (-1.79, -0.48)	
p-value [3]		0.231		<0.001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.7.2.5a
Summary of PGIC by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Degree of Change	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	32	41	76	
Mean (StdDev)	4.7 (1.19)	3.7 (1.54)	4.8 (1.57)	3.7 (1.78)	
Median	5.0	3.0	5.0	3.0	
Min, Max	3, 7	1, 8	2, 9	0, 9	
LS Mean (StdErr) [2]	4.77 (0.384)	3.67 (0.276)	4.89 (0.284)	3.80 (0.225)	
95% CI [2]	3.99, 5.54	3.12, 4.23	4.32, 5.45	3.36, 4.25	
Difference (95% CI) [2]		-1.09 (-1.95, -0.24)		-1.08 (-1.74, -0.43)	
p-value [3]		0.013		0.001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.7.2.5a
Summary of PGIC by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Degree of Change	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	19	33	39	77	
Mean (StdDev)	4.9 (1.31)	3.8 (1.62)	4.8 (1.75)	3.8 (1.92)	
Median	5.0	3.0	5.0	4.0	
Min, Max	2, 7	1, 8	0, 8	0, 9	
LS Mean (StdErr) [2]	4.77 (0.406)	3.66 (0.291)	4.78 (0.317)	3.84 (0.246)	
95% CI [2]	3.96, 5.59	3.07, 4.24	4.16, 5.41	3.35, 4.32	
Difference (95% CI) [2]		-1.12 (-2.01, -0.22)		-0.95 (-1.68, -0.22)	
p-value [3]		0.016		0.011	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
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Table 35.2.7.2.5a
Summary of PGIC by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Degree of Change	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	18	35	40	76	
Mean (StdDev)	5.0 (1.37)	3.5 (1.27)	4.9 (1.69)	3.7 (2.07)	
Median	5.5	3.0	5.0	4.0	
Min, Max	2, 7	1, 7	1, 8	0, 9	
LS Mean (StdErr) [2]	4.93 (0.356)	3.47 (0.248)	4.85 (0.334)	3.74 (0.263)	
95% CI [2]	4.21, 5.64	2.97, 3.97	4.19, 5.52	3.22, 4.26	
Difference (95% CI) [2]		-1.46 (-2.23, -0.68)		-1.11 (-1.87, -0.35)	
Hedges'G (95% CI)		-0.97 (-1.63, -0.40)		-0.50 (-0.90, -0.11)	
p-value [3]		<0.001		0.004	
					0.561

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-pp-ism-a.sas Date: 15:50/07AUG2023

Table 35.2.7.2.6a
Summary of PGIC by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	12	25	51	94	
Mean (StdDev)	3.5 (1.57)	3.0 (1.49)	2.4 (1.39)	3.3 (1.70)	
Median	3.5	2.0	2.0	3.0	
Min, Max	1, 6	1, 6	1, 6	1, 7	
LS Mean (StdErr) [2]	3.51 (0.505)	3.04 (0.312)	2.37 (0.227)	3.28 (0.179)	
95% CI [2]	2.48, 4.53	2.41, 3.68	1.92, 2.82	2.93, 3.64	
Difference (95% CI) [2]		-0.46 (-1.62, 0.69)		0.91 (0.36, 1.47)	
p-value [3]		0.420		0.001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-pp-tryp-a.sas Date: 15:51/07AUG2023

Table 35.2.7.2.6a
Summary of PGIC by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	24	49	86	
Mean (StdDev)	3.2 (1.59)	3.3 (1.58)	2.9 (1.63)	4.2 (1.74)	
Median	3.0	4.0	2.0	5.0	
Min, Max	2, 7	1, 6	1, 6	1, 7	
LS Mean (StdErr) [2]	3.21 (0.490)	3.33 (0.336)	2.88 (0.250)	4.20 (0.197)	
95% CI [2]	2.21, 4.21	2.64, 4.01	2.38, 3.37	3.81, 4.59	
Difference (95% CI) [2]		0.12 (-1.04, 1.27)		1.32 (0.72, 1.93)	
p-value [3]		0.839		<0.0001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-pp-tryp-a.sas Date: 15:51/07AUG2023

Table 35.2.7.2.6a
Summary of PGIC by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	11	22	45	90	
Mean (StdDev)	2.8 (1.47)	3.5 (1.74)	2.7 (1.80)	4.3 (1.67)	
Median	2.0	3.0	2.0	5.0	
Min, Max	1, 6	1, 6	1, 7	1, 7	
LS Mean (StdErr) [2]	2.81 (0.550)	3.50 (0.379)	2.71 (0.262)	4.31 (0.194)	
95% CI [2]	1.69, 3.94	2.72, 4.27	2.19, 3.22	3.93, 4.70	
Difference (95% CI) [2]		0.68 (-0.60, 1.97)		1.61 (0.99, 2.23)	
p-value [3]		0.285		<0.0001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-pp-tryp-a.sas Date: 15:51/07AUG2023

Table 35.2.7.2.6a
Summary of PGIC by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	25	48	83	
Mean (StdDev)	3.0 (1.48)	3.8 (1.71)	2.5 (1.74)	4.4 (1.74)	
Median	2.5	4.0	2.0	5.0	
Min, Max	1, 6	1, 6	1, 6	1, 7	
LS Mean (StdErr) [2]	3.17 (0.516)	3.87 (0.340)	2.49 (0.257)	4.37 (0.206)	
95% CI [2]	2.12, 4.22	3.18, 4.56	1.98, 3.00	3.97, 4.78	
Difference (95% CI) [2]		0.70 (-0.50, 1.90)		1.89 (1.26, 2.52)	
p-value [3]		0.243		<0.0001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-pp-tryp-a.sas Date: 15:51/07AUG2023

Table 35.2.7.2.6a
Summary of PGIC by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	25	46	85	
Mean (StdDev)	2.9 (1.68)	3.6 (1.75)	2.5 (1.67)	4.4 (1.82)	
Median	2.0	4.0	2.0	5.0	
Min, Max	1, 7	1, 6	1, 7	1, 7	
LS Mean (StdErr) [2]	3.20 (0.535)	3.76 (0.353)	2.50 (0.265)	4.49 (0.206)	
95% CI [2]	2.12, 4.29	3.04, 4.48	1.98, 3.03	4.08, 4.89	
Difference (95% CI) [2]		0.56 (-0.69, 1.80)		1.98 (1.34, 2.63)	
p-value [3]		0.369		<0.0001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-pp-tryp-a.sas Date: 15:51/07AUG2023

Table 35.2.7.2.6a
Summary of PGIC by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	11	24	47	87	
Mean (StdDev)	3.3 (1.79)	3.7 (1.81)	2.7 (1.88)	4.4 (1.67)	
Median	3.0	4.0	2.0	5.0	
Min, Max	1, 7	1, 6	1, 7	1, 7	
LS Mean (StdErr) [2]	3.42 (0.589)	3.73 (0.381)	2.68 (0.261)	4.45 (0.199)	
95% CI [2]	2.22, 4.62	2.95, 4.50	2.16, 3.19	4.06, 4.84	
Difference (95% CI) [2]		0.30 (-1.07, 1.68)		1.77 (1.14, 2.40)	
Hedges'G (95% CI)		0.16 (-0.58, 0.91)		0.96 (0.60, 1.35)	
p-value [3]		0.658		<0.0001	
					0.051

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-pp-tryp-a.sas Date: 15:51/07AUG2023

Table 35.2.7.2.6a
Summary of PGIC by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Degree of Change	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	12	25	51	94	
Mean (StdDev)	4.1 (1.00)	4.5 (1.08)	4.5 (1.19)	4.2 (1.67)	
Median	4.0	5.0	5.0	4.0	
Min, Max	3, 6	2, 6	0, 8	0, 8	
LS Mean (StdErr) [2]	4.33 (0.342)	4.54 (0.212)	4.54 (0.217)	4.22 (0.170)	
95% CI [2]	3.64, 5.03	4.11, 4.97	4.11, 4.97	3.89, 4.56	
Difference (95% CI) [2]		0.21 (-0.58, 0.99)		-0.32 (-0.85, 0.21)	
p-value [3]		0.593		0.234	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-pp-tryp-a.sas Date: 15:51/07AUG2023

Table 35.2.7.2.6a
Summary of PGIC by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Degree of Change	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	24	49	85	
Mean (StdDev)	4.2 (1.41)	4.0 (1.12)	4.5 (1.37)	3.6 (1.74)	
Median	4.0	4.0	5.0	3.0	
Min, Max	1, 6	2, 6	1, 7	0, 9	
LS Mean (StdErr) [2]	4.16 (0.380)	3.96 (0.260)	4.47 (0.238)	3.55 (0.188)	
95% CI [2]	3.38, 4.93	3.43, 4.49	4.00, 4.94	3.18, 3.92	
Difference (95% CI) [2]		-0.20 (-1.09, 0.70)		-0.92 (-1.50, -0.34)	
p-value [3]		0.657		0.002	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-pp-tryp-a.sas Date: 15:51/07AUG2023

Table 35.2.7.2.6a
Summary of PGIC by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Degree of Change	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	11	22	45	90	
Mean (StdDev)	3.8 (1.83)	4.3 (1.25)	4.9 (1.53)	3.6 (1.65)	
Median	4.0	4.0	5.0	4.0	
Min, Max	1, 7	2, 7	1, 8	0, 9	
LS Mean (StdErr) [2]	3.68 (0.481)	4.24 (0.331)	4.91 (0.246)	3.60 (0.182)	
95% CI [2]	2.69, 4.66	3.56, 4.91	4.43, 5.40	3.24, 3.96	
Difference (95% CI) [2]		0.56 (-0.56, 1.68)		-1.32 (-1.90, -0.73)	
p-value [3]		0.316		<0.0001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-pp-tryp-a.sas Date: 15:51/07AUG2023

Table 35.2.7.2.6a
Summary of PGIC by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Degree of Change	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	25	48	83	
Mean (StdDev)	4.4 (1.78)	4.2 (1.12)	4.9 (1.37)	3.5 (1.82)	
Median	4.5	4.0	5.0	3.0	
Min, Max	2, 9	2, 7	2, 7	0, 9	
LS Mean (StdErr) [2]	4.25 (0.427)	4.13 (0.281)	4.86 (0.246)	3.52 (0.197)	
95% CI [2]	3.39, 5.12	3.56, 4.70	4.37, 5.34	3.13, 3.91	
Difference (95% CI) [2]		-0.12 (-1.11, 0.87)		-1.33 (-1.94, -0.73)	
p-value [3]		0.804		<0.0001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-pp-tryp-a.sas Date: 15:51/07AUG2023

Table 35.2.7.2.6a
Summary of PGIC by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Degree of Change	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	25	46	85	
Mean (StdDev)	4.1 (1.62)	4.0 (1.54)	5.0 (1.57)	3.7 (1.90)	
Median	5.0	4.0	5.0	3.0	
Min, Max	0, 6	1, 8	1, 8	0, 9	
LS Mean (StdErr) [2]	3.88 (0.490)	3.95 (0.323)	5.04 (0.269)	3.75 (0.209)	
95% CI [2]	2.88, 4.88	3.30, 4.61	4.50, 5.57	3.34, 4.17	
Difference (95% CI) [2]		0.07 (-1.06, 1.21)		-1.28 (-1.94, -0.63)	
p-value [3]		0.895		<0.001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-pp-tryp-a.sas Date: 15:51/07AUG2023

Table 35.2.7.2.6a
Summary of PGIC by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Degree of Change	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	11	24	47	87	
Mean (StdDev)	4.0 (1.55)	4.0 (1.62)	5.1 (1.54)	3.6 (1.91)	
Median	4.0	4.0	5.0	3.0	
Min, Max	1, 6	1, 9	2, 8	0, 9	
LS Mean (StdErr) [2]	3.82 (0.518)	3.93 (0.335)	5.10 (0.268)	3.56 (0.204)	
95% CI [2]	2.77, 4.88	3.25, 4.61	4.57, 5.63	3.16, 3.97	
Difference (95% CI) [2]		0.11 (-1.10, 1.31)		-1.53 (-2.18, -0.89)	
Hedges'G (95% CI)		0.06 (-0.67, 0.81)		-0.81 (-1.20, -0.45)	
p-value [3]		0.859		<0.0001	
					0.030

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-pp-tryp-a.sas Date: 15:51/07AUG2023

Table 35.2.7.2.7a
Summary of PGIC by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	59	111	4	8	
Mean (StdDev)	2.6 (1.46)	3.3 (1.64)	2.5 (1.91)	2.9 (1.89)	
Median	2.0	3.0	2.0	2.0	
Min, Max	1, 6	1, 7	1, 5	1, 6	
LS Mean (StdErr) [2]	2.64 (0.231)	3.31 (0.181)	1.88 (1.506)	2.21 (1.187)	
95% CI [2]	2.18, 3.09	2.95, 3.67	-1.59, 5.36	-0.53, 4.94	
Difference (95% CI) [2]		0.67 (0.17, 1.18)		0.32 (-2.70, 3.34)	
p-value [3]		0.009		0.811	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-pp-ecog-a.sas Date: 15:51/07AUG2023

Table 35.2.7.2.7a
Summary of PGIC by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	58	102	4	8	
Mean (StdDev)	2.9 (1.61)	4.0 (1.76)	3.5 (1.91)	3.6 (1.30)	
Median	2.0	4.5	3.0	4.0	
Min, Max	1, 7	1, 7	2, 6	1, 5	
LS Mean (StdErr) [2]	2.79 (0.250)	3.91 (0.200)	3.65 (1.228)	3.62 (0.968)	
95% CI [2]	2.29, 3.28	3.51, 4.30	0.81, 6.48	1.38, 5.85	
Difference (95% CI) [2]		1.12 (0.57, 1.68)		-0.03 (-2.49, 2.43)	
p-value [3]		<0.001		0.979	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-pp-ecog-a.sas Date: 15:51/07AUG2023

Table 35.2.7.2.7a
Summary of PGIC by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	52	104	4	8	
Mean (StdDev)	2.8 (1.72)	4.2 (1.73)	2.0 (2.00)	4.3 (1.39)	
Median	2.0	5.0	1.0	5.0	
Min, Max	1, 7	1, 7	1, 5	2, 6	
LS Mean (StdErr) [2]	2.64 (0.267)	4.00 (0.208)	1.24 (1.262)	3.59 (0.995)	
95% CI [2]	2.11, 3.16	3.59, 4.41	-1.67, 4.15	1.29, 5.88	
Difference (95% CI) [2]		1.36 (0.78, 1.94)		2.35 (-0.18, 4.88)	
p-value [3]		<0.0001		0.064	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
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Table 35.2.7.2.7a
Summary of PGIC by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	56	100	4	8	
Mean (StdDev)	2.6 (1.70)	4.3 (1.76)	2.5 (1.73)	3.6 (1.51)	
Median	2.0	5.0	2.0	4.0	
Min, Max	1, 6	1, 7	1, 5	1, 5	
LS Mean (StdErr) [2]	2.54 (0.259)	4.24 (0.204)	2.24 (1.262)	3.59 (0.995)	
95% CI [2]	2.03, 3.05	3.83, 4.64	-0.67, 5.15	1.29, 5.88	
Difference (95% CI) [2]		1.70 (1.12, 2.27)		1.35 (-1.18, 3.88)	
p-value [3]		<0.0001		0.253	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
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Table 35.2.7.2.7a
Summary of PGIC by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	101	4	9	
Mean (StdDev)	2.6 (1.68)	4.3 (1.84)	2.5 (1.73)	3.8 (1.72)	
Median	2.0	5.0	2.0	5.0	
Min, Max	1, 7	1, 7	1, 5	2, 6	
LS Mean (StdErr) [2]	2.51 (0.267)	4.25 (0.208)	1.55 (1.307)	3.15 (1.036)	
95% CI [2]	1.99, 3.04	3.84, 4.67	-1.41, 4.51	0.81, 5.49	
Difference (95% CI) [2]		1.74 (1.14, 2.34)		1.60 (-0.95, 4.15)	
p-value [3]		<0.0001		0.190	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
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Table 35.2.7.2.7a
Summary of PGIC by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	54	102	4	9	
Mean (StdDev)	2.8 (1.87)	4.3 (1.71)	2.3 (1.89)	3.6 (1.81)	
Median	2.0	5.0	1.5	4.0	
Min, Max	1, 7	1, 7	1, 5	1, 6	
LS Mean (StdErr) [2]	2.76 (0.269)	4.27 (0.206)	0.80 (1.330)	2.40 (1.054)	
95% CI [2]	2.23, 3.29	3.86, 4.68	-2.21, 3.81	0.02, 4.78	
Difference (95% CI) [2]		1.51 (0.92, 2.10)		1.60 (-0.99, 4.19)	
Hedges'G (95% CI)		0.73 (0.40, 1.09)		0.49 (-0.74, 1.95)	
p-value [3]		<0.0001		0.196	
					0.906

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
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Table 35.2.7.2.7a
Summary of PGIC by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Degree of Change	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	59	111	4	8	
Mean (StdDev)	4.4 (1.09)	4.3 (1.56)	5.0 (2.16)	4.6 (1.77)	
Median	5.0	5.0	4.5	4.0	
Min, Max	0, 6	0, 8	3, 8	2, 8	
LS Mean (StdErr) [2]	4.46 (0.206)	4.29 (0.162)	4.74 (1.530)	4.59 (1.206)	
95% CI [2]	4.05, 4.86	3.97, 4.61	1.21, 8.26	1.81, 7.37	
Difference (95% CI) [2]		-0.16 (-0.61, 0.29)		-0.15 (-3.22, 2.92)	
p-value [3]		0.479		0.915	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
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Table 35.2.7.2.7a
Summary of PGIC by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Degree of Change	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	58	101	4	8	
Mean (StdDev)	4.4 (1.38)	3.6 (1.55)	4.3 (1.50)	5.0 (2.07)	
Median	5.0	3.0	5.0	4.0	
Min, Max	1, 7	0, 9	2, 5	2, 8	
LS Mean (StdErr) [2]	4.48 (0.219)	3.60 (0.175)	3.63 (1.551)	4.46 (1.223)	
95% CI [2]	4.05, 4.91	3.26, 3.95	0.06, 7.21	1.64, 7.28	
Difference (95% CI) [2]		-0.88 (-1.36, -0.39)		0.82 (-2.29, 3.93)	
p-value [3]		<0.001		0.558	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
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Table 35.2.7.2.7a
Summary of PGIC by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Degree of Change	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	52	104	4	8	
Mean (StdDev)	4.7 (1.66)	3.8 (1.63)	5.5 (1.29)	3.8 (1.04)	
Median	5.0	4.0	5.5	4.0	
Min, Max	1, 8	0, 9	4, 7	2, 5	
LS Mean (StdErr) [2]	4.65 (0.255)	3.75 (0.198)	6.21 (0.853)	4.26 (0.673)	
95% CI [2]	4.14, 5.15	3.36, 4.15	4.24, 8.17	2.71, 5.82	
Difference (95% CI) [2]		-0.89 (-1.45, -0.34)		-1.94 (-3.65, -0.23)	
p-value [3]		0.002		0.031	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
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Table 35.2.7.2.7a
Summary of PGIC by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Degree of Change	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	56	100	4	8	
Mean (StdDev)	4.8 (1.46)	3.6 (1.66)	5.0 (1.63)	4.5 (2.14)	
Median	5.0	3.0	5.0	4.0	
Min, Max	2, 9	0, 9	3, 7	2, 8	
LS Mean (StdErr) [2]	4.84 (0.235)	3.69 (0.185)	3.82 (1.312)	4.06 (1.034)	
95% CI [2]	4.38, 5.31	3.32, 4.05	0.80, 6.85	1.67, 6.44	
Difference (95% CI) [2]		-1.15 (-1.67, -0.63)		0.24 (-2.40, 2.87)	
p-value [3]		<0.0001		0.842	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
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Table 35.2.7.2.7a
Summary of PGIC by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Degree of Change	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	101	4	9	
Mean (StdDev)	4.8 (1.65)	3.8 (1.82)	4.8 (1.26)	4.3 (1.87)	
Median	5.0	4.0	5.0	4.0	
Min, Max	0, 8	0, 9	3, 6	2, 7	
LS Mean (StdErr) [2]	4.79 (0.265)	3.71 (0.207)	5.28 (1.308)	5.08 (1.037)	
95% CI [2]	4.27, 5.32	3.31, 4.12	2.32, 8.23	2.73, 7.42	
Difference (95% CI) [2]		-1.08 (-1.67, -0.49)		-0.20 (-2.75, 2.35)	
p-value [3]		<0.001		0.863	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
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Table 35.2.7.2.7a
Summary of PGIC by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Degree of Change	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	54	102	4	9	
Mean (StdDev)	4.9 (1.63)	3.6 (1.80)	5.5 (0.58)	4.0 (2.50)	
Median	5.0	3.0	5.5	4.0	
Min, Max	1, 8	0, 9	5, 6	0, 9	
LS Mean (StdErr) [2]	4.82 (0.266)	3.61 (0.204)	5.97 (1.705)	4.18 (1.351)	
95% CI [2]	4.29, 5.35	3.20, 4.01	2.12, 9.83	1.12, 7.23	
Difference (95% CI) [2]		-1.21 (-1.80, -0.63)		-1.80 (-5.13, 1.53)	
Hedges'G (95% CI)		-0.60 (-0.94, -0.26)		-0.43 (-1.87, 0.81)	
p-value [3]		<0.0001		0.252	
					0.780

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
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Table 35.2.7.2.8a
Summary of PGIC by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	60	109	
Mean (StdDev)	2.0 (0.00)	2.9 (1.52)	2.6 (1.51)	3.3 (1.67)	
Median	2.0	2.5	2.0	3.0	
Min, Max	2, 2	1, 6	1, 6	1, 7	
LS Mean (StdErr) [2]	2.14 (0.917)	3.18 (0.811)	2.64 (0.236)	3.29 (0.186)	
95% CI [2]	0.07, 4.22	1.35, 5.02	2.17, 3.10	2.93, 3.66	
Difference (95% CI) [2]		1.04 (-1.33, 3.41)		0.65 (0.14, 1.17)	
p-value [3]		0.346		0.013	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
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Table 35.2.7.2.8a
Summary of PGIC by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	10	59	100	
Mean (StdDev)	2.7 (1.15)	3.7 (1.83)	2.9 (1.64)	4.0 (1.73)	
Median	2.0	4.5	2.0	4.0	
Min, Max	2, 4	1, 6	1, 7	1, 7	
LS Mean (StdErr) [2]	2.71 (1.161)	3.78 (1.027)	2.81 (0.249)	3.89 (0.200)	
95% CI [2]	0.09, 5.34	1.45, 6.10	2.32, 3.30	3.49, 4.28	
Difference (95% CI) [2]		1.06 (-1.94, 4.06)		1.08 (0.53, 1.63)	
p-value [3]		0.445		<0.001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
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Table 35.2.7.2.8a
Summary of PGIC by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	2	9	54	103	
Mean (StdDev)	2.0 (0.00)	4.2 (1.86)	2.8 (1.76)	4.2 (1.70)	
Median	2.0	5.0	2.0	5.0	
Min, Max	2, 2	1, 6	1, 7	1, 7	
LS Mean (StdErr) [2]	2.72 (1.406)	4.09 (0.938)	2.57 (0.262)	3.96 (0.207)	
95% CI [2]	-0.60, 6.05	1.87, 6.31	2.05, 3.08	3.55, 4.37	
Difference (95% CI) [2]		1.37 (-2.13, 4.87)		1.39 (0.82, 1.96)	
p-value [3]		0.386		<0.0001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
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Table 35.2.7.2.8a
Summary of PGIC by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	8	57	100	
Mean (StdDev)	2.7 (2.08)	4.6 (2.00)	2.6 (1.69)	4.2 (1.73)	
Median	2.0	5.5	2.0	5.0	
Min, Max	1, 5	1, 6	1, 6	1, 7	
LS Mean (StdErr) [2]	2.14 (1.150)	3.47 (1.015)	2.54 (0.255)	4.18 (0.202)	
95% CI [2]	-0.58, 4.86	1.07, 5.87	2.04, 3.05	3.78, 4.57	
Difference (95% CI) [2]		1.33 (-1.79, 4.46)		1.63 (1.07, 2.20)	
p-value [3]		0.347		<0.0001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
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Table 35.2.7.2.8a
Summary of PGIC by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	55	101	
Mean (StdDev)	1.7 (0.58)	4.4 (2.13)	2.6 (1.69)	4.2 (1.81)	
Median	2.0	6.0	2.0	5.0	
Min, Max	1, 2	1, 6	1, 7	1, 7	
LS Mean (StdErr) [2]	1.22 (1.107)	3.41 (0.978)	2.55 (0.264)	4.19 (0.206)	
95% CI [2]	-1.33, 3.78	1.16, 5.67	2.03, 3.07	3.79, 4.60	
Difference (95% CI) [2]		2.19 (-0.74, 5.11)		1.65 (1.06, 2.23)	
p-value [3]		0.123		<0.0001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.7.2.8a
Summary of PGIC by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	8	55	103	
Mean (StdDev)	2.3 (1.53)	5.0 (1.31)	2.8 (1.89)	4.2 (1.74)	
Median	2.0	5.5	2.0	4.0	
Min, Max	1, 4	3, 6	1, 7	1, 7	
LS Mean (StdErr) [2]	1.67 (0.570)	3.67 (0.503)	2.76 (0.273)	4.17 (0.210)	
95% CI [2]	0.32, 3.01	2.48, 4.86	2.22, 3.30	3.75, 4.58	
Difference (95% CI) [2]		2.00 (0.45, 3.55)		1.41 (0.81, 2.00)	
Hedges'G (95% CI)		1.37 (0.04, 3.46)		0.67 (0.34, 1.02)	
p-value [3]		0.018		<0.0001	
					0.310

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
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Table 35.2.7.2.8a
Summary of PGIC by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Degree of Change	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	60	109	
Mean (StdDev)	5.3 (0.58)	4.1 (1.97)	4.4 (1.17)	4.3 (1.54)	
Median	5.0	4.5	5.0	4.0	
Min, Max	5, 6	1, 8	0, 8	0, 8	
LS Mean (StdErr) [2]	5.14 (1.168)	3.76 (1.033)	4.46 (0.208)	4.35 (0.164)	
95% CI [2]	2.50, 7.78	1.42, 6.09	4.05, 4.87	4.02, 4.67	
Difference (95% CI) [2]		-1.39 (-4.41, 1.63)		-0.12 (-0.57, 0.34)	
p-value [3]		0.326		0.614	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
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Table 35.2.7.2.8a
Summary of PGIC by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Degree of Change	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	10	59	99	
Mean (StdDev)	5.0 (1.00)	3.6 (1.43)	4.4 (1.39)	3.7 (1.65)	
Median	5.0	3.5	5.0	4.0	
Min, Max	4, 6	1, 5	1, 7	0, 9	
LS Mean (StdErr) [2]	5.25 (0.878)	4.11 (0.777)	4.39 (0.230)	3.67 (0.185)	
95% CI [2]	3.26, 7.24	2.35, 5.86	3.93, 4.84	3.30, 4.03	
Difference (95% CI) [2]		-1.14 (-3.41, 1.13)		-0.72 (-1.23, -0.21)	
p-value [3]		0.284		0.006	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
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Table 35.2.7.2.8a
Summary of PGIC by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Degree of Change	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	2	9	54	103	
Mean (StdDev)	5.5 (2.12)	3.8 (1.64)	4.7 (1.63)	3.8 (1.60)	
Median	5.5	3.0	5.0	4.0	
Min, Max	4, 7	2, 7	1, 8	0, 9	
LS Mean (StdErr) [2]	6.29 (1.452)	4.24 (0.969)	4.66 (0.248)	3.74 (0.196)	
95% CI [2]	2.86, 9.72	1.95, 6.53	4.17, 5.15	3.35, 4.12	
Difference (95% CI) [2]		-2.05 (-5.67, 1.56)		-0.93 (-1.46, -0.39)	
p-value [3]		0.221		<0.001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
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Table 35.2.7.2.8a
Summary of PGIC by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Degree of Change	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	8	57	100	
Mean (StdDev)	5.3 (0.58)	4.1 (1.55)	4.7 (1.48)	3.6 (1.71)	
Median	5.0	4.0	5.0	3.0	
Min, Max	5, 6	2, 7	2, 9	0, 9	
LS Mean (StdErr) [2]	5.35 (0.967)	4.18 (0.854)	4.84 (0.243)	3.73 (0.192)	
95% CI [2]	3.06, 7.63	2.16, 6.20	4.36, 5.32	3.35, 4.11	
Difference (95% CI) [2]		-1.17 (-3.79, 1.46)		-1.11 (-1.65, -0.57)	
p-value [3]		0.329		<0.0001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
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Table 35.2.7.2.8a
Summary of PGIC by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Degree of Change	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	55	101	
Mean (StdDev)	6.0 (1.00)	4.3 (2.12)	4.8 (1.62)	3.8 (1.80)	
Median	6.0	5.0	5.0	4.0	
Min, Max	5, 7	1, 8	0, 8	0, 9	
LS Mean (StdErr) [2]	5.72 (1.148)	3.91 (1.015)	4.78 (0.262)	3.77 (0.205)	
95% CI [2]	3.08, 8.37	1.57, 6.25	4.26, 5.30	3.36, 4.17	
Difference (95% CI) [2]		-1.81 (-4.85, 1.22)		-1.01 (-1.59, -0.43)	
p-value [3]		0.206		<0.001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
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Table 35.2.7.2.8a
Summary of PGIC by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Degree of Change	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	8	55	103	
Mean (StdDev)	6.0 (1.00)	3.3 (1.67)	4.8 (1.60)	3.7 (1.87)	
Median	6.0	3.0	5.0	4.0	
Min, Max	5, 7	2, 7	1, 8	0, 9	
LS Mean (StdErr) [2]	5.82 (1.003)	2.99 (0.886)	4.81 (0.272)	3.68 (0.210)	
95% CI [2]	3.45, 8.19	0.89, 5.08	4.27, 5.35	3.26, 4.09	
Difference (95% CI) [2]		-2.83 (-5.56, -0.11)		-1.13 (-1.73, -0.54)	
Hedges'G (95% CI)		-1.10 (-3.06, 0.24)		-0.54 (-0.88, -0.21)	
p-value [3]		0.044		<0.001	
					0.187

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-pp-thpy-a.sas Date: 15:51/07AUG2023

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Table 35.2.7.3.2a
Proportion of Patients with PGIC at Least Moderately Better (PGIC >= 5) at C7D1
Per Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with PGIC >= 5 at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Overall	13/ 67 (19.4) (10.8, 30.9)	57/123 (46.3) (37.3, 55.6)	3.50 (1.67, 7.72) <0.001	2.35 (1.40, 3.94) 0.001	0.27 (0.14, 0.40) <0.0001	
Age Group (Years)						0.964
< 65	12/ 56 (21.4) (11.6, 34.4)	51/117 (43.6) (34.4, 53.1)	2.77 (1.27, 6.31) 0.006	2.01 (1.17, 3.45) 0.011	0.22 (0.08, 0.36) 0.002	
>= 65	1/ 11 (9.1) (0.2, 41.3)	6/ 6 (100.0) (54.1, 100.0)	NE (2.95, NE) 0.002	22.00 (0.51, 945.61) 0.107	0.95 (0.87, 1.00) <0.0001	
Sex						0.262
Male	5/ 15 (33.3) (11.8, 61.6)	17/ 35 (48.6) (31.4, 66.0)	1.78 (0.45, 7.86) 0.358	1.42 (0.65, 3.09) 0.375	0.15 (-0.16, 0.45) 0.343	
Female	8/ 52 (15.4) (6.9, 28.1)	40/ 88 (45.5) (34.8, 56.4)	4.58 (1.85, 12.82) <0.001	3.00 (1.51, 5.98) 0.002	0.31 (0.16, 0.45) <0.0001	

Abbreviations: PGIC = Patients Global Impression of Change, CI = Confidence Interval
PGIC: 1=No change, 2=Almost the same, 3=A little Better, 4=Somewhat better, 5=Moderately better, 6=Better, 7=A great deal better
Note: Patient reached C7D1 or EOS prior to C7D1 with missing C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.7.3.2a
Proportion of Patients with PGIC at Least Moderately Better (PGIC >= 5) at C7D1
Per Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with PGIC >= 5 at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Region						0.758
North America	7/ 32 (21.9) (9.3, 40.0)	28/ 52 (53.8) (39.5, 67.8)	4.11 (1.30, 12.79) 0.007	2.36 (1.20, 4.64) 0.013	0.31 (0.11, 0.52) 0.003	
Europe	6/ 35 (17.1) (6.6, 33.6)	29/ 71 (40.8) (29.3, 53.2)	3.55 (1.20, 11.53) 0.012	2.44 (1.13, 5.28) 0.024	0.25 (0.08, 0.41) 0.004	
Country						NA
BEL	0/ 1 (0.0) (0.0, 97.5)	0/ 2 (0.0) (0.0, 84.2)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
CAN	1/ 5 (20.0) (0.5, 71.6)	6/ 8 (75.0) (34.9, 96.8)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
CHE	0/ 1 (0.0) (0.0, 97.5)	1/ 2 (50.0) (1.3, 98.7)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
DEU	5/ 14 (35.7) (12.8, 64.9)	3/ 17 (17.6) (3.8, 43.4)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	

Abbreviations: PGIC = Patients Global Impression of Change, CI = Confidence Interval
PGIC: 1=No change, 2=Almost the same, 3=A little Better, 4=Somewhat better, 5=Moderately better, 6=Better, 7=A great deal better
Note: Patient reached C7D1 or EOS prior to C7D1 with missing C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.7.3.2a
Proportion of Patients with PGIC at Least Moderately Better (PGIC >= 5) at C7D1
Per Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with PGIC >= 5 at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
DNK	0/0	1/ 1 (100.0) (2.5, 100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
ESP	0/ 3 (0.0) (0.0, 70.8)	7/ 13 (53.8) (25.1, 80.8)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
FRA	0/ 5 (0.0) (0.0, 52.2)	5/ 10 (50.0) (18.7, 81.3)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
GBR	0/ 5 (0.0) (0.0, 52.2)	5/ 10 (50.0) (18.7, 81.3)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
ITA	0/0	1/ 3 (33.3) (0.8, 90.6)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
NLD	0/ 3 (0.0) (0.0, 70.8)	3/ 7 (42.9) (9.9, 81.6)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
NOR	1/ 2 (50.0) (1.3, 98.7)	2/ 5 (40.0) (5.3, 85.3)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	

Abbreviations: PGIC = Patients Global Impression of Change, CI = Confidence Interval
PGIC: 1=No change, 2=Almost the same, 3=A little Better, 4=Somewhat better, 5=Moderately better, 6=Better, 7=A great deal better
Note: Patient reached C7D1 or EOS prior to C7D1 with missing C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.7.3.2a
Proportion of Patients with PGIC at Least Moderately Better (PGIC >= 5) at C7D1
Per Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with PGIC >= 5 at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
SWE	0/ 1 (0.0) (0.0, 97.5)	1/ 1 (100.0) (2.5, 100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
USA	6/ 27 (22.2) (8.6, 42.3)	22/ 44 (50.0) (34.6, 65.4)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
Baseline ISM Status						0.691
Moderate	4/ 22 (18.2) (5.2, 40.3)	18/ 37 (48.6) (31.9, 65.6)	4.06 (1.06, 20.80) 0.022	2.59 (1.05, 6.41) 0.040	0.31 (0.07, 0.55) 0.012	
Severe	9/ 45 (20.0) (9.6, 34.6)	39/ 86 (45.3) (34.6, 56.5)	3.27 (1.32, 8.54) 0.005	2.24 (1.19, 4.21) 0.012	0.25 (0.09, 0.41) 0.002	
Baseline Serum Tryptase (ng/mL)						0.412
< 20	3/ 13 (23.1) (5.0, 53.8)	10/ 26 (38.5) (20.2, 59.4)	1.88 (0.34, 13.32) 0.422	1.54 (0.53, 4.46) 0.425	0.13 (-0.18, 0.44) 0.398	
>= 20	10/ 54 (18.5) (9.3, 31.4)	47/ 97 (48.5) (38.2, 58.8)	4.11 (1.77, 10.14) <0.001	2.60 (1.44, 4.71) 0.002	0.30 (0.16, 0.44) <0.0001	

Abbreviations: PGIC = Patients Global Impression of Change, CI = Confidence Interval
PGIC: 1=No change, 2=Almost the same, 3=A little Better, 4=Somewhat better, 5=Moderately better, 6=Better, 7=A great deal better
Note: Patient reached C7D1 or EOS prior to C7D1 with missing C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.7.3.2a
Proportion of Patients with PGIC at Least Moderately Better (PGIC >= 5) at C7D1
Per Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with PGIC >= 5 at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
ECOG Status						0.522
0 or 1	12/ 63 (19.0) (10.2, 30.9)	54/114 (47.4) (37.9, 56.9)	3.75 (1.73, 8.51) <0.001	2.45 (1.43, 4.21) 0.001	0.28 (0.15, 0.42) <0.0001	
2+	1/ 4 (25.0) (0.6, 80.6)	3/ 9 (33.3) (7.5, 70.1)	1.50 (0.06, 98.22) 0.757	1.33 (0.24, 7.28) 0.740	0.10 (-0.51, 0.71) 0.748	
Prior TKI therapy						0.978
Yes	0/ 3 (0.0) (0.0, 70.8)	6/ 10 (60.0) (26.2, 87.8)	NE (0.27, NE) 0.156	NE (NE, NE) NE	0.47 (0.06, 0.88) 0.026	
No	13/ 64 (20.3) (11.3, 32.2)	51/113 (45.1) (35.8, 54.8)	3.16 (1.49, 7.08) 0.001	2.20 (1.31, 3.69) 0.003	0.25 (0.11, 0.39) <0.001	

Abbreviations: PGIC = Patients Global Impression of Change, CI = Confidence Interval
PGIC: 1=No change, 2=Almost the same, 3=A little Better, 4=Somewhat better, 5=Moderately better, 6=Better, 7=A great deal better
Note: Patient reached C7D1 or EOS prior to C7D1 with missing C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.7.3.4a
Proportion of Patients with PGIC Degree of Change <=1.5 at C7D1
Per Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with PGIC Degree of Change <= 1.5 at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Overall	1/ 67 (1.5) (0.0, 8.0)	9/123 (7.3) (3.4, 13.4)	4.69 (0.59, 205.24) 0.124	4.69 (0.50, 43.81) 0.175	0.05 (-0.00, 0.11) 0.060	
Age Group (Years)						0.978
< 65	1/ 56 (1.8) (0.0, 9.6)	7/117 (6.0) (2.4, 11.9)	3.42 (0.40, 154.72) 0.242	3.42 (0.36, 32.04) 0.281	0.04 (-0.01, 0.09) 0.155	
>= 65	0/ 11 (0.0) (0.0, 28.5)	2/ 6 (33.3) (4.3, 77.7)	NE (0.17, NE) 0.237	NE (NE, NE) NE	0.27 (-0.13, 0.68) 0.188	
Sex						0.982
Male	0/ 15 (0.0) (0.0, 21.8)	1/ 35 (2.9) (0.1, 14.9)	NE (0.02, NE) 0.508	NE (NE, NE) NE	0.03 (-0.03, 0.09) 0.312	
Female	1/ 52 (1.9) (0.0, 10.3)	8/ 88 (9.1) (4.0, 17.1)	4.38 (0.52, 192.68) 0.153	4.38 (0.45, 42.93) 0.205	0.06 (-0.01, 0.13) 0.087	

Abbreviations: PGIC = Patients Global Impression of Change, CI = Confidence Interval
PGIC: 1=No change, 2=Almost the same, 3=A little Better, 4=Somewhat better, 5=Moderately better, 6=Better, 7=A great deal better
Note: Patient reached C7D1 or EOS prior to C7D1 with missing C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgicdc-resp-pp-a.sas Date: 11:54/10AUG2023

Table 35.2.7.3.4a
Proportion of Patients with PGIC Degree of Change <=1.5 at C7D1
Per Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with PGIC Degree of Change <= 1.5 at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Region						0.965
North America	1/ 32 (3.1) (0.1, 16.2)	2/ 52 (3.8) (0.5, 13.2)	1.06 (0.04, 74.63) 0.974	1.06 (0.04, 28.46) 0.974	0.00 (-0.07, 0.07) 0.970	
Europe	0/ 35 (0.0) (0.0, 10.0)	7/ 71 (9.9) (4.1, 19.3)	NE (0.99, NE) 0.050	NE (NE, NE) NE	0.10 (0.03, 0.17) 0.006	
Country						NA
BEL	0/ 1 (0.0) (0.0, 97.5)	0/ 2 (0.0) (0.0, 84.2)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
CAN	0/ 5 (0.0) (0.0, 52.2)	1/ 8 (12.5) (0.3, 52.7)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
CHE	0/ 1 (0.0) (0.0, 97.5)	0/ 2 (0.0) (0.0, 84.2)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
DEU	0/ 14 (0.0) (0.0, 23.2)	1/ 17 (5.9) (0.1, 28.7)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	

Abbreviations: PGIC = Patients Global Impression of Change, CI = Confidence Interval
PGIC: 1=No change, 2=Almost the same, 3=A little Better, 4=Somewhat better, 5=Moderately better, 6=Better, 7=A great deal better
Note: Patient reached C7D1 or EOS prior to C7D1 with missing C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.7.3.4a
Proportion of Patients with PGIC Degree of Change <=1.5 at C7D1
Per Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with PGIC Degree of Change <= 1.5 at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
DNK	0/0	1/ 1 (100.0) (2.5, 100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
ESP	0/ 3 (0.0) (0.0, 70.8)	1/ 13 (7.7) (0.2, 36.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
FRA	0/ 5 (0.0) (0.0, 52.2)	2/ 10 (20.0) (2.5, 55.6)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
GBR	0/ 5 (0.0) (0.0, 52.2)	1/ 10 (10.0) (0.3, 44.5)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
ITA	0/0	0/ 3 (0.0) (0.0, 70.8)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
NLD	0/ 3 (0.0) (0.0, 70.8)	1/ 7 (14.3) (0.4, 57.9)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
NOR	0/ 2 (0.0) (0.0, 84.2)	0/ 5 (0.0) (0.0, 52.2)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	

Abbreviations: PGIC = Patients Global Impression of Change, CI = Confidence Interval
PGIC: 1=No change, 2=Almost the same, 3=A little Better, 4=Somewhat better, 5=Moderately better, 6=Better, 7=A great deal better
Note: Patient reached C7D1 or EOS prior to C7D1 with missing C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.7.3.4a
Proportion of Patients with PGIC Degree of Change <=1.5 at C7D1
Per Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with PGIC Degree of Change <= 1.5 at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
SWE	0/ 1 (0.0) (0.0, 97.5)	0/ 1 (0.0) (0.0, 97.5)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
USA	1/ 27 (3.7) (0.1, 19.0)	1/ 44 (2.3) (0.1, 12.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
Baseline ISM Status						0.979
Moderate	0/ 22 (0.0) (0.0, 15.4)	1/ 37 (2.7) (0.1, 14.2)	NE (0.01, NE) 0.655	NE (NE, NE) NE	0.01 (-0.03, 0.05) 0.514	
Severe	1/ 45 (2.2) (0.1, 11.8)	8/ 86 (9.3) (4.1, 17.5)	4.41 (0.55, 197.33) 0.140	4.41 (0.48, 40.94) 0.191	0.07 (-0.01, 0.14) 0.071	
Baseline Serum Tryptase (ng/mL)						0.971
< 20	1/ 13 (7.7) (0.2, 36.0)	1/ 26 (3.8) (0.1, 19.6)	0.28 (0.00, 34.77) 0.490	0.28 (0.01, 13.17) >0.999	-0.05 (-0.21, 0.10) 0.513	
>= 20	0/ 54 (0.0) (0.0, 6.6)	8/ 97 (8.2) (3.6, 15.6)	NE (1.13, NE) 0.041	NE (NE, NE) NE	0.08 (0.02, 0.13) 0.005	

Abbreviations: PGIC = Patients Global Impression of Change, CI = Confidence Interval
PGIC: 1=No change, 2=Almost the same, 3=A little Better, 4=Somewhat better, 5=Moderately better, 6=Better, 7=A great deal better
Note: Patient reached C7D1 or EOS prior to C7D1 with missing C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.7.3.4a
Proportion of Patients with PGIC Degree of Change <=1.5 at C7D1
Per Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with PGIC Degree of Change <= 1.5 at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
ECOG Status						0.977
0 or 1	1/ 63 (1.6) (0.0, 8.5)	8/114 (7.0) (3.1, 13.4)	4.33 (0.52, 189.06) 0.156	4.33 (0.45, 42.04) 0.206	0.05 (-0.01, 0.10) 0.086	
2+	0/ 4 (0.0) (0.0, 60.2)	1/ 9 (11.1) (0.3, 48.2)	NE (0.02, NE) 0.564	NE (NE, NE) NE	0.10 (-0.12, 0.32) 0.380	
Prior TKI therapy						0.996
Yes	0/ 3 (0.0) (0.0, 70.8)	0/ 10 (0.0) (0.0, 30.8)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
No	1/ 64 (1.6) (0.0, 8.4)	9/113 (8.0) (3.7, 14.6)	5.00 (0.64, 221.94) 0.103	5.00 (0.54, 46.13) 0.156	0.06 (0.00, 0.12) 0.049	

Abbreviations: PGIC = Patients Global Impression of Change, CI = Confidence Interval
PGIC: 1=No change, 2=Almost the same, 3=A little Better, 4=Somewhat better, 5=Moderately better, 6=Better, 7=A great deal better
Note: Patient reached C7D1 or EOS prior to C7D1 with missing C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.6.2.1a
Summary of PGIS by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	54	113	11	6	
Mean (StdDev)	2.7 (0.90)	2.8 (0.92)	2.9 (1.04)	2.3 (0.52)	
Median	3.0	3.0	3.0	2.0	
Min, Max	1, 4	1, 4	1, 4	2, 3	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
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Table 35.2.6.2.1a
Summary of PGIS by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	54	113	11	6	
Mean (StdDev)	2.3 (0.71)	2.2 (0.93)	2.6 (0.92)	2.0 (0.63)	
Median	2.0	2.0	3.0	2.0	
Min, Max	1, 4	0, 4	1, 4	1, 3	
C2D1 CFB					
n	52	110	11	6	
LS Mean (StdErr) [2]	-0.35 (0.153)	-0.54 (0.113)	-0.28 (0.535)	-0.78 (0.781)	
95% CI [2]	-0.65, -0.04	-0.76, -0.32	-1.44, 0.88	-2.47, 0.91	
Difference (95% CI) in CFB [2]		-0.20 (-0.52, 0.13)		-0.50 (-1.81, 0.81)	
p-value [3]		0.237		0.425	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
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Table 35.2.6.2.1a
Summary of PGIS by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	53	104	10	6	
Mean (StdDev)	2.4 (0.84)	2.0 (0.87)	2.8 (0.79)	1.5 (0.55)	
Median	2.0	2.0	3.0	1.5	
Min, Max	1, 4	0, 4	2, 4	1, 2	
C3D1 CFB					
n	51	103	10	6	
LS Mean (StdErr) [2]	-0.23 (0.172)	-0.73 (0.126)	-0.01 (0.554)	-0.87 (0.802)	
95% CI [2]	-0.57, 0.11	-0.98, -0.48	-1.22, 1.20	-2.62, 0.87	
Difference (95% CI) in CFB [2]		-0.51 (-0.87, -0.14)		-0.86 (-2.23, 0.50)	
p-value [3]		0.007		0.193	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
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Table 35.2.6.2.1a
Summary of PGIS by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	49	106	7	6	
Mean (StdDev)	2.3 (0.84)	2.0 (0.82)	2.9 (1.07)	1.2 (0.75)	
Median	2.0	2.0	3.0	1.0	
Min, Max	1, 4	0, 4	1, 4	0, 2	
C4D1 CFB					
n	47	104	7	6	
LS Mean (StdErr) [2]	-0.30 (0.175)	-0.70 (0.126)	-0.08 (0.564)	-1.08 (0.925)	
95% CI [2]	-0.64, 0.05	-0.95, -0.45	-1.36, 1.19	-3.17, 1.01	
Difference (95% CI) in CFB [2]		-0.41 (-0.77, -0.04)		-1.00 (-2.82, 0.82)	
p-value [3]		0.030		0.244	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
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Table 35.2.6.2.1a
Summary of PGIS by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	51	104	9	5	
Mean (StdDev)	2.2 (0.86)	1.9 (0.78)	2.9 (0.78)	1.0 (1.00)	
Median	2.0	2.0	3.0	1.0	
Min, Max	1, 4	0, 4	2, 4	0, 2	
C5D1 CFB					
n	50	100	9	5	
LS Mean (StdErr) [2]	-0.33 (0.169)	-0.74 (0.125)	0.10 (0.633)	-1.27 (0.971)	
95% CI [2]	-0.67, 0.00	-0.99, -0.50	-1.31, 1.51	-3.44, 0.89	
Difference (95% CI) in CFB [2]		-0.41 (-0.77, -0.05)		-1.37 (-3.14, 0.40)	
p-value [3]		0.027		0.116	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
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Table 35.2.6.2.1a
Summary of PGIS by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	50	105	8	6	
Mean (StdDev)	2.3 (0.80)	2.0 (0.89)	2.8 (1.04)	1.0 (0.63)	
Median	2.0	2.0	3.0	1.0	
Min, Max	1, 4	1, 4	1, 4	0, 2	
C6D1 CFB					
n	49	101	8	6	
LS Mean (StdErr) [2]	-0.33 (0.168)	-0.71 (0.123)	-0.06 (0.486)	-1.18 (0.806)	
95% CI [2]	-0.66, 0.01	-0.95, -0.47	-1.15, 1.02	-2.97, 0.62	
Difference (95% CI) in CFB [2]		-0.38 (-0.74, -0.02)		-1.11 (-2.66, 0.44)	
p-value [3]		0.037		0.141	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
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Table 35.2.6.2.1a
Summary of PGIS by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	48	105	10	6	
Mean (StdDev)	2.2 (0.85)	1.9 (0.93)	2.7 (0.95)	1.2 (0.75)	
Median	2.0	2.0	3.0	1.0	
Min, Max	1, 4	0, 4	1, 4	0, 2	
C7D1 CFB					
n	47	101	10	6	
LS Mean (StdErr) [2]	-0.24 (0.176)	-0.65 (0.126)	-0.12 (0.563)	-1.39 (0.815)	
95% CI [2]	-0.59, 0.11	-0.90, -0.40	-1.35, 1.10	-3.16, 0.39	
Difference (95% CI) in CFB [2]		-0.40 (-0.78, -0.03)		-1.26 (-2.65, 0.12)	
Hedges'G (95% CI) in CFB		-0.32 (-0.68, 0.02)		-0.64 (-1.89, 0.39)	
p-value [3]		0.034		0.070	
					0.320

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-pp-age-a.sas Date: 15:48/07AUG2023

Table 35.2.6.2.2a
Summary of PGIS by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	14	32	51	87	
Mean (StdDev)	2.5 (0.94)	2.4 (0.88)	2.8 (0.91)	2.9 (0.90)	
Median	2.5	2.0	3.0	3.0	
Min, Max	1, 4	1, 4	1, 4	1, 4	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-pp-sex-a.sas Date: 15:48/07AUG2023

Table 35.2.6.2.2a
Summary of PGIS by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	14	33	51	86	
Mean (StdDev)	2.2 (0.80)	2.2 (0.92)	2.4 (0.74)	2.2 (0.92)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	1, 4	1, 4	0, 4	
C2D1 CFB					
n	13	31	50	85	
LS Mean (StdErr) [2]	-0.09 (0.262)	-0.24 (0.174)	-0.40 (0.163)	-0.66 (0.139)	
95% CI [2]	-0.62, 0.44	-0.59, 0.11	-0.72, -0.08	-0.94, -0.39	
Difference (95% CI) in CFB [2]		-0.15 (-0.72, 0.43)		-0.26 (-0.62, 0.09)	
p-value [3]		0.609		0.145	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-pp-sex-a.sas Date: 15:48/07AUG2023

Table 35.2.6.2.2a
Summary of PGIS by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	28	48	82	
Mean (StdDev)	2.2 (0.86)	2.1 (0.66)	2.5 (0.82)	1.9 (0.92)	
Median	2.0	2.0	3.0	2.0	
Min, Max	1, 4	1, 3	1, 4	0, 4	
C3D1 CFB					
n	14	28	47	81	
LS Mean (StdErr) [2]	-0.24 (0.258)	-0.42 (0.181)	-0.14 (0.186)	-0.82 (0.154)	
95% CI [2]	-0.77, 0.28	-0.79, -0.06	-0.51, 0.23	-1.12, -0.51	
Difference (95% CI) in CFB [2]		-0.18 (-0.75, 0.39)		-0.67 (-1.08, -0.27)	
p-value [3]		0.529		0.001	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-pp-sex-a.sas Date: 15:48/07AUG2023

Table 35.2.6.2.2a
Summary of PGIS by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	13	30	43	82	
Mean (StdDev)	2.3 (0.95)	2.0 (0.67)	2.4 (0.87)	1.9 (0.89)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	1, 4	1, 4	0, 4	
C4D1 CFB					
n	12	29	42	81	
LS Mean (StdErr) [2]	-0.14 (0.337)	-0.48 (0.233)	-0.27 (0.178)	-0.76 (0.143)	
95% CI [2]	-0.82, 0.54	-0.95, -0.01	-0.62, 0.08	-1.05, -0.48	
Difference (95% CI) in CFB [2]		-0.34 (-1.07, 0.39)		-0.49 (-0.87, -0.11)	
p-value [3]		0.353		0.012	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-pp-sex-a.sas Date: 15:48/07AUG2023

Table 35.2.6.2.2a
Summary of PGIS by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	31	45	78	
Mean (StdDev)	2.2 (0.86)	1.8 (0.75)	2.4 (0.88)	1.9 (0.83)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	1, 4	1, 4	0, 4	
C5D1 CFB					
n	14	28	45	77	
LS Mean (StdErr) [2]	-0.04 (0.272)	-0.49 (0.192)	-0.28 (0.184)	-0.82 (0.153)	
95% CI [2]	-0.59, 0.51	-0.88, -0.10	-0.65, 0.08	-1.12, -0.51	
Difference (95% CI) in CFB [2]		-0.45 (-1.04, 0.15)		-0.53 (-0.94, -0.13)	
p-value [3]		0.137		0.010	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-pp-sex-a.sas Date: 15:48/07AUG2023

Table 35.2.6.2.2a
Summary of PGIS by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	13	32	45	79	
Mean (StdDev)	2.5 (0.88)	1.7 (0.77)	2.3 (0.84)	2.0 (0.94)	
Median	3.0	2.0	2.0	2.0	
Min, Max	1, 4	1, 4	1, 4	0, 4	
C6D1 CFB					
n	12	29	45	78	
LS Mean (StdErr) [2]	0.08 (0.313)	-0.62 (0.209)	-0.35 (0.173)	-0.73 (0.144)	
95% CI [2]	-0.55, 0.72	-1.04, -0.20	-0.70, -0.01	-1.02, -0.45	
Difference (95% CI) in CFB [2]		-0.70 (-1.38, -0.02)		-0.38 (-0.76, 0.00)	
p-value [3]		0.043		0.051	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
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Table 35.2.6.2.2a
Summary of PGIS by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	14	34	44	77	
Mean (StdDev)	2.4 (0.93)	1.8 (0.90)	2.3 (0.87)	1.9 (0.95)	
Median	2.5	2.0	2.0	2.0	
Min, Max	1, 4	1, 4	1, 4	0, 4	
C7D1 CFB					
n	13	31	44	76	
LS Mean (StdErr) [2]	0.20 (0.302)	-0.39 (0.197)	-0.32 (0.187)	-0.78 (0.154)	
95% CI [2]	-0.41, 0.81	-0.78, 0.01	-0.69, 0.05	-1.09, -0.48	
Difference (95% CI) in CFB [2]		-0.58 (-1.24, 0.08)		-0.47 (-0.87, -0.06)	
Hedges'G (95% CI) in CFB		-0.52 (-1.23, 0.13)		-0.36 (-0.74, 0.02)	
p-value [3]		0.081		0.023	
					0.827

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-pp-sex-a.sas Date: 15:48/07AUG2023

Table 35.2.6.2.3a
Summary of PGIS by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	30	49	35	70	
Mean (StdDev)	2.6 (0.93)	2.5 (0.94)	2.9 (0.90)	2.9 (0.86)	
Median	2.5	2.0	3.0	3.0	
Min, Max	1, 4	1, 4	1, 4	1, 4	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-pp-reg-a.sas Date: 15:48/07AUG2023

Table 35.2.6.2.3a
Summary of PGIS by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	30	51	35	68	
Mean (StdDev)	2.2 (0.79)	2.0 (0.96)	2.5 (0.70)	2.3 (0.87)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	1, 4	1, 4	
C2D1 CFB					
n	28	48	35	68	
LS Mean (StdErr) [2]	-0.34 (0.212)	-0.55 (0.177)	-0.33 (0.188)	-0.54 (0.146)	
95% CI [2]	-0.76, 0.08	-0.90, -0.19	-0.70, 0.04	-0.83, -0.25	
Difference (95% CI) in CFB [2]		-0.21 (-0.68, 0.26)		-0.21 (-0.62, 0.20)	
p-value [3]		0.380		0.309	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-pp-reg-a.sas Date: 15:48/07AUG2023

Table 35.2.6.2.3a
Summary of PGIS by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	29	44	34	66	
Mean (StdDev)	2.2 (0.79)	1.9 (0.80)	2.6 (0.85)	2.0 (0.90)	
Median	2.0	2.0	3.0	2.0	
Min, Max	1, 4	0, 4	1, 4	0, 4	
C3D1 CFB					
n	27	43	34	66	
LS Mean (StdErr) [2]	-0.23 (0.217)	-0.65 (0.183)	-0.14 (0.218)	-0.79 (0.164)	
95% CI [2]	-0.66, 0.21	-1.01, -0.28	-0.57, 0.29	-1.12, -0.47	
Difference (95% CI) in CFB [2]		-0.42 (-0.90, 0.06)		-0.66 (-1.13, -0.18)	
p-value [3]		0.086		0.007	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-pp-reg-a.sas Date: 15:48/07AUG2023

Table 35.2.6.2.3a
Summary of PGIS by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	22	43	34	69	
Mean (StdDev)	2.2 (0.85)	1.8 (0.71)	2.5 (0.90)	2.0 (0.89)	
Median	2.0	2.0	2.5	2.0	
Min, Max	1, 4	1, 4	1, 4	0, 4	
C4D1 CFB					
n	20	42	34	68	
LS Mean (StdErr) [2]	-0.16 (0.252)	-0.57 (0.203)	-0.32 (0.209)	-0.78 (0.157)	
95% CI [2]	-0.67, 0.34	-0.98, -0.17	-0.73, 0.09	-1.10, -0.47	
Difference (95% CI) in CFB [2]		-0.41 (-0.94, 0.11)		-0.46 (-0.92, -0.01)	
p-value [3]		0.123		0.045	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-pp-reg-a.sas Date: 15:48/07AUG2023

Table 35.2.6.2.3a
Summary of PGIS by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	26	41	34	68	
Mean (StdDev)	2.0 (0.96)	1.8 (0.71)	2.5 (0.75)	1.9 (0.86)	
Median	2.0	2.0	3.0	2.0	
Min, Max	1, 4	0, 4	1, 4	0, 4	
C5D1 CFB					
n	25	38	34	67	
LS Mean (StdErr) [2]	-0.31 (0.232)	-0.62 (0.196)	-0.19 (0.213)	-0.82 (0.162)	
95% CI [2]	-0.78, 0.15	-1.01, -0.23	-0.62, 0.23	-1.14, -0.50	
Difference (95% CI) in CFB [2]		-0.31 (-0.83, 0.21)		-0.63 (-1.09, -0.16)	
p-value [3]		0.235		0.008	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
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Table 35.2.6.2.3a
Summary of PGIS by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	24	44	34	67	
Mean (StdDev)	2.3 (0.94)	1.7 (0.67)	2.4 (0.78)	2.1 (1.00)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	1, 3	1, 4	0, 4	
C6D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-0.11 (0.211)	-0.77 (0.175)	-0.40 (0.214)	-0.70 (0.161)	
95% CI [2]	-0.53, 0.31	-1.12, -0.42	-0.83, 0.02	-1.02, -0.38	
Difference (95% CI) in CFB [2]		-0.66 (-1.13, -0.19)		-0.30 (-0.76, 0.17)	
p-value [3]		0.007		0.211	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
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Table 35.2.6.2.3a
Summary of PGIS by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	24	44	34	67	
Mean (StdDev)	2.1 (0.97)	1.6 (0.84)	2.4 (0.79)	2.1 (0.95)	
Median	2.0	1.0	2.5	2.0	
Min, Max	1, 4	0, 4	1, 4	0, 4	
C7D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-0.06 (0.250)	-0.68 (0.200)	-0.27 (0.212)	-0.64 (0.160)	
95% CI [2]	-0.56, 0.44	-1.08, -0.28	-0.69, 0.16	-0.96, -0.33	
Difference (95% CI) in CFB [2]		-0.62 (-1.15, -0.09)		-0.38 (-0.84, 0.08)	
Hedges'G (95% CI) in CFB		-0.49 (-1.04, 0.02)		-0.29 (-0.72, 0.12)	
p-value [3]		0.022		0.107	
					0.510

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
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Table 35.2.6.2.4a
Summary of PGIS by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
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Table 35.2.6.2.4a
Summary of PGIS by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
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Table 35.2.6.2.4a
Summary of PGIS by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
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Table 35.2.6.2.4a
Summary of PGIS by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
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Table 35.2.6.2.4a
Summary of PGIS by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
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Table 35.2.6.2.5a
Summary of PGIS by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	21	35	44	84	
Mean (StdDev)	2.7 (1.11)	2.5 (0.89)	2.8 (0.82)	2.8 (0.90)	
Median	2.0	2.0	3.0	3.0	
Min, Max	1, 4	1, 4	1, 4	1, 4	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
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Table 35.2.6.2.5a
Summary of PGIS by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	21	35	44	84	
Mean (StdDev)	2.1 (0.79)	1.9 (0.85)	2.4 (0.73)	2.3 (0.92)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	1, 4	1, 4	
C2D1 CFB					
n	20	34	43	82	
LS Mean (StdErr) [2]	-0.07 (0.234)	-0.51 (0.162)	-0.37 (0.167)	-0.54 (0.135)	
95% CI [2]	-0.54, 0.40	-0.83, -0.18	-0.70, -0.04	-0.81, -0.28	
Difference (95% CI) in CFB [2]		-0.43 (-0.93, 0.06)		-0.17 (-0.56, 0.22)	
p-value [3]		0.086		0.383	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
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Table 35.2.6.2.5a
Summary of PGIS by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	18	33	45	77	
Mean (StdDev)	2.5 (0.86)	1.7 (0.73)	2.4 (0.84)	2.1 (0.89)	
Median	2.0	2.0	3.0	2.0	
Min, Max	1, 4	0, 3	1, 4	0, 4	
C3D1 CFB					
n	17	33	44	76	
LS Mean (StdErr) [2]	0.26 (0.262)	-0.65 (0.173)	-0.33 (0.181)	-0.79 (0.150)	
95% CI [2]	-0.27, 0.79	-1.00, -0.31	-0.69, 0.02	-1.09, -0.50	
Difference (95% CI) in CFB [2]		-0.91 (-1.47, -0.36)		-0.46 (-0.88, -0.04)	
p-value [3]		0.002		0.034	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
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Table 35.2.6.2.5a
Summary of PGIS by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	17	33	39	79	
Mean (StdDev)	2.2 (1.07)	1.8 (0.68)	2.4 (0.79)	2.0 (0.88)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 3	1, 4	0, 4	
C4D1 CFB					
n	16	32	38	78	
LS Mean (StdErr) [2]	-0.07 (0.261)	-0.53 (0.179)	-0.34 (0.191)	-0.82 (0.148)	
95% CI [2]	-0.60, 0.45	-0.89, -0.16	-0.72, 0.04	-1.12, -0.53	
Difference (95% CI) in CFB [2]		-0.45 (-0.99, 0.09)		-0.48 (-0.92, -0.05)	
p-value [3]		0.099		0.030	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
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Table 35.2.6.2.5a
Summary of PGIS by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	32	41	77	
Mean (StdDev)	2.2 (0.96)	1.9 (0.71)	2.4 (0.83)	1.9 (0.85)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	1, 3	1, 4	0, 4	
C5D1 CFB					
n	18	30	41	75	
LS Mean (StdErr) [2]	-0.05 (0.246)	-0.48 (0.172)	-0.36 (0.189)	-0.94 (0.150)	
95% CI [2]	-0.54, 0.45	-0.83, -0.14	-0.73, 0.01	-1.23, -0.64	
Difference (95% CI) in CFB [2]		-0.44 (-0.96, 0.09)		-0.58 (-1.02, -0.14)	
p-value [3]		0.101		0.010	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.6.2.5a
Summary of PGIS by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	19	33	39	78	
Mean (StdDev)	2.2 (1.01)	1.7 (0.63)	2.4 (0.75)	2.0 (0.99)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	1, 3	1, 4	0, 4	
C6D1 CFB					
n	18	31	39	76	
LS Mean (StdErr) [2]	-0.04 (0.228)	-0.62 (0.159)	-0.35 (0.189)	-0.78 (0.147)	
95% CI [2]	-0.50, 0.42	-0.93, -0.30	-0.72, 0.03	-1.08, -0.49	
Difference (95% CI) in CFB [2]		-0.57 (-1.06, -0.09)		-0.44 (-0.87, -0.00)	
p-value [3]		0.021		0.049	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
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Table 35.2.6.2.5a
Summary of PGIS by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	18	35	40	76	
Mean (StdDev)	2.1 (0.94)	1.8 (0.99)	2.4 (0.84)	1.9 (0.91)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	1, 4	0, 4	
C7D1 CFB					
n	17	33	40	74	
LS Mean (StdErr) [2]	-0.04 (0.268)	-0.42 (0.182)	-0.25 (0.189)	-0.81 (0.149)	
95% CI [2]	-0.58, 0.50	-0.78, -0.05	-0.62, 0.13	-1.10, -0.51	
Difference (95% CI) in CFB [2]		-0.37 (-0.94, 0.19)		-0.56 (-0.99, -0.13)	
Hedges'G (95% CI) in CFB		-0.35 (-0.97, 0.24)		-0.44 (-0.85, -0.06)	
p-value [3]		0.186		0.011	
					0.471

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-pp-ism-a.sas Date: 15:48/07AUG2023

Table 35.2.6.2.7a
Summary of PGIS by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	61	110	4	9	
Mean (StdDev)	2.7 (0.92)	2.7 (0.91)	3.3 (0.96)	3.1 (0.78)	
Median	3.0	3.0	3.5	3.0	
Min, Max	1, 4	1, 4	2, 4	2, 4	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
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Table 35.2.6.2.7a
Summary of PGIS by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	61	111	4	8	
Mean (StdDev)	2.3 (0.76)	2.2 (0.92)	2.5 (0.58)	2.3 (0.89)	
Median	2.0	2.0	2.5	2.0	
Min, Max	1, 4	0, 4	2, 3	1, 4	
C2D1 CFB					
n	59	108	4	8	
LS Mean (StdErr) [2]	-0.31 (0.145)	-0.53 (0.116)	-0.81 (0.617)	-0.90 (0.486)	
95% CI [2]	-0.60, -0.03	-0.76, -0.30	-2.23, 0.61	-2.02, 0.22	
Difference (95% CI) in CFB [2]		-0.21 (-0.53, 0.11)		-0.09 (-1.32, 1.15)	
p-value [3]		0.188		0.873	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
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Table 35.2.6.2.7a
Summary of PGIS by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	59	102	4	8	
Mean (StdDev)	2.4 (0.84)	1.9 (0.83)	2.5 (1.00)	2.5 (1.07)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	2, 4	1, 4	
C3D1 CFB					
n	57	101	4	8	
LS Mean (StdErr) [2]	-0.13 (0.159)	-0.74 (0.125)	-0.99 (0.990)	-0.84 (0.781)	
95% CI [2]	-0.45, 0.18	-0.99, -0.49	-3.27, 1.30	-2.64, 0.96	
Difference (95% CI) in CFB [2]		-0.61 (-0.95, -0.26)		0.15 (-1.84, 2.13)	
p-value [3]		<0.001		0.869	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
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Table 35.2.6.2.7a
Summary of PGIS by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	52	103	4	9	
Mean (StdDev)	2.3 (0.90)	1.9 (0.82)	2.8 (0.50)	2.4 (0.88)	
Median	2.0	2.0	3.0	2.0	
Min, Max	1, 4	0, 4	2, 3	1, 4	
C4D1 CFB					
n	50	101	4	9	
LS Mean (StdErr) [2]	-0.26 (0.166)	-0.73 (0.127)	-0.10 (0.861)	-0.30 (0.682)	
95% CI [2]	-0.58, 0.07	-0.98, -0.48	-2.05, 1.85	-1.84, 1.24	
Difference (95% CI) in CFB [2]		-0.48 (-0.83, -0.12)		-0.20 (-1.88, 1.48)	
p-value [3]		0.009		0.794	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-pp-ecog-a.sas Date: 15:48/07AUG2023

Table 35.2.6.2.7a
Summary of PGIS by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	56	100	4	9	
Mean (StdDev)	2.3 (0.89)	1.9 (0.77)	2.5 (0.58)	2.2 (1.20)	
Median	2.0	2.0	2.5	2.0	
Min, Max	1, 4	0, 4	2, 3	0, 4	
C5D1 CFB					
n	55	96	4	9	
LS Mean (StdErr) [2]	-0.19 (0.158)	-0.74 (0.125)	-1.90 (0.927)	-1.70 (0.735)	
95% CI [2]	-0.50, 0.12	-0.98, -0.49	-4.00, 0.20	-3.36, -0.04	
Difference (95% CI) in CFB [2]		-0.54 (-0.89, -0.20)		0.20 (-1.61, 2.01)	
p-value [3]		0.002		0.808	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
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Table 35.2.6.2.7a
Summary of PGIS by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	102	4	9	
Mean (StdDev)	2.3 (0.83)	1.9 (0.87)	3.0 (0.82)	2.7 (1.00)	
Median	2.0	2.0	3.0	3.0	
Min, Max	1, 4	0, 4	2, 4	1, 4	
C6D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-0.27 (0.153)	-0.75 (0.120)	-0.02 (1.111)	-0.33 (0.880)	
95% CI [2]	-0.58, 0.03	-0.99, -0.51	-2.54, 2.49	-2.32, 1.67	
Difference (95% CI) in CFB [2]		-0.48 (-0.81, -0.14)		-0.30 (-2.47, 1.87)	
p-value [3]		0.006		0.761	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
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Table 35.2.6.2.7a
Summary of PGIS by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	54	102	4	9	
Mean (StdDev)	2.3 (0.90)	1.8 (0.90)	2.5 (0.58)	2.7 (1.00)	
Median	2.0	2.0	2.5	3.0	
Min, Max	1, 4	0, 4	2, 3	1, 4	
C7D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-0.15 (0.164)	-0.69 (0.126)	-0.53 (0.869)	-0.32 (0.689)	
95% CI [2]	-0.48, 0.17	-0.94, -0.44	-2.49, 1.44	-1.88, 1.23	
Difference (95% CI) in CFB [2]		-0.54 (-0.90, -0.18)		0.20 (-1.50, 1.90)	
Hedges'G (95% CI) in CFB		-0.44 (-0.78, -0.10)		0.09 (-1.21, 1.44)	
p-value [3]		0.003		0.796	
					0.213

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-pp-ecog-a.sas Date: 15:48/07AUG2023

Table 35.2.6.2.8a
Summary of PGIS by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	62	109	
Mean (StdDev)	3.0 (1.00)	3.2 (0.92)	2.7 (0.92)	2.7 (0.90)	
Median	3.0	3.5	3.0	3.0	
Min, Max	2, 4	2, 4	1, 4	1, 4	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
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Table 35.2.6.2.8a
Summary of PGIS by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	62	109	
Mean (StdDev)	2.3 (1.15)	2.5 (0.97)	2.3 (0.74)	2.1 (0.91)	
Median	3.0	2.0	2.0	2.0	
Min, Max	1, 3	1, 4	1, 4	0, 4	
C2D1 CFB					
n	3	10	60	106	
LS Mean (StdErr) [2]	-0.75 (0.722)	-0.89 (0.638)	-0.31 (0.144)	-0.52 (0.115)	
95% CI [2]	-2.38, 0.88	-2.34, 0.55	-0.59, -0.02	-0.75, -0.30	
Difference (95% CI) in CFB [2]		-0.14 (-2.01, 1.72)		-0.22 (-0.53, 0.09)	
p-value [3]		0.866		0.171	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-pp-thpy-a.sas Date: 15:48/07AUG2023

Table 35.2.6.2.8a
Summary of PGIS by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	10	60	100	
Mean (StdDev)	2.3 (1.15)	2.2 (0.79)	2.5 (0.83)	1.9 (0.87)	
Median	3.0	2.0	2.0	2.0	
Min, Max	1, 3	1, 4	1, 4	0, 4	
C3D1 CFB					
n	3	10	58	99	
LS Mean (StdErr) [2]	-0.61 (0.718)	-0.85 (0.635)	-0.15 (0.161)	-0.71 (0.127)	
95% CI [2]	-2.23, 1.02	-2.29, 0.58	-0.46, 0.17	-0.96, -0.46	
Difference (95% CI) in CFB [2]		-0.24 (-2.10, 1.61)		-0.56 (-0.91, -0.21)	
p-value [3]		0.772		0.002	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
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Table 35.2.6.2.8a
Summary of PGIS by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	2	9	54	103	
Mean (StdDev)	3.0 (0.00)	2.1 (0.93)	2.3 (0.89)	1.9 (0.82)	
Median	3.0	2.0	2.0	2.0	
Min, Max	3, 3	1, 4	1, 4	0, 4	
C4D1 CFB					
n	2	9	52	101	
LS Mean (StdErr) [2]	-0.72 (0.915)	-1.09 (0.611)	-0.25 (0.164)	-0.68 (0.128)	
95% CI [2]	-2.89, 1.44	-2.54, 0.35	-0.57, 0.08	-0.93, -0.42	
Difference (95% CI) in CFB [2]		-0.37 (-2.65, 1.91)		-0.43 (-0.78, -0.08)	
p-value [3]		0.713		0.017	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
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Table 35.2.6.2.8a
Summary of PGIS by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	8	57	101	
Mean (StdDev)	2.0 (1.00)	1.9 (0.64)	2.3 (0.87)	1.9 (0.82)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 3	1, 3	1, 4	0, 4	
C5D1 CFB					
n	3	8	56	97	
LS Mean (StdErr) [2]	-0.65 (0.627)	-0.82 (0.554)	-0.22 (0.161)	-0.72 (0.128)	
95% CI [2]	-2.14, 0.83	-2.13, 0.49	-0.54, 0.10	-0.97, -0.46	
Difference (95% CI) in CFB [2]		-0.17 (-1.87, 1.54)		-0.50 (-0.85, -0.15)	
p-value [3]		0.824		0.006	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
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Table 35.2.6.2.8a
Summary of PGIS by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	55	102	
Mean (StdDev)	2.7 (0.58)	2.1 (1.17)	2.3 (0.86)	1.9 (0.88)	
Median	3.0	2.0	2.0	2.0	
Min, Max	2, 3	1, 4	1, 4	0, 4	
C6D1 CFB					
n	3	9	54	98	
LS Mean (StdErr) [2]	-0.32 (0.794)	-1.06 (0.702)	-0.26 (0.157)	-0.69 (0.123)	
95% CI [2]	-2.15, 1.51	-2.68, 0.56	-0.57, 0.05	-0.93, -0.45	
Difference (95% CI) in CFB [2]		-0.74 (-2.84, 1.36)		-0.43 (-0.77, -0.08)	
p-value [3]		0.439		0.015	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-pp-thpy-a.sas Date: 15:48/07AUG2023

Table 35.2.6.2.8a
Summary of PGIS by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	8	55	103	
Mean (StdDev)	2.7 (0.58)	1.8 (0.71)	2.3 (0.89)	1.9 (0.95)	
Median	3.0	2.0	2.0	2.0	
Min, Max	2, 3	1, 3	1, 4	0, 4	
C7D1 CFB					
n	3	8	54	99	
LS Mean (StdErr) [2]	-0.25 (0.570)	-1.25 (0.503)	-0.19 (0.167)	-0.62 (0.129)	
95% CI [2]	-1.60, 1.10	-2.44, -0.06	-0.52, 0.14	-0.88, -0.37	
Difference (95% CI) in CFB [2]		-1.00 (-2.55, 0.55)		-0.43 (-0.79, -0.07)	
Hedges'G (95% CI) in CFB		-0.68 (-2.46, 0.70)		-0.34 (-0.68, -0.01)	
p-value [3]		0.170		0.018	
					0.457

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
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Table 35.2.6.3.2a
Proportion of Patients with PGIS Change from Baseline <= -1 at C7D1
Per Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with PGIS Change from Baseline <= -1 at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Overall	23/ 67 (34.3) (23.2, 46.9)	65/123 (52.8) (43.6, 61.9)	2.41 (1.23, 4.78) 0.006	1.61 (1.12, 2.33) 0.011	0.21 (0.07, 0.35) 0.004	
Age Group (Years)						0.226
< 65	21/ 56 (37.5) (24.9, 51.5)	61/117 (52.1) (42.7, 61.5)	2.00 (0.98, 4.13) 0.041	1.44 (0.99, 2.11) 0.056	0.16 (0.01, 0.32) 0.036	
>= 65	2/ 11 (18.2) (2.3, 51.8)	4/ 6 (66.7) (22.3, 95.7)	6.00 (0.32, 353.65) 0.142	6.00 (0.19, 187.42) 0.308	0.45 (-0.13, 1.00) 0.128	
Sex						0.695
Male	5/ 15 (33.3) (11.8, 61.6)	16/ 35 (45.7) (28.8, 63.4)	2.09 (0.48, 9.83) 0.276	1.50 (0.69, 3.24) 0.303	0.16 (-0.12, 0.45) 0.250	
Female	18/ 52 (34.6) (22.0, 49.1)	49/ 88 (55.7) (44.7, 66.3)	2.48 (1.15, 5.49) 0.012	1.65 (1.08, 2.52) 0.021	0.22 (0.05, 0.39) 0.009	

Abbreviations: PGIS = Patients Global Impression of Symptom Severity, CI = Confidence Interval
PGIS: 0=Absent, 1=Minimal, 2=Moderate, 3=Severe, 4=Very Severe
Note: Patient reached C7D1 or EOS prior to C7D1 with missing C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.6.3.2a
Proportion of Patients with PGIS Change from Baseline <= -1 at C7D1
Per Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with PGIS Change from Baseline <= -1 at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Region						0.261
North America	8/ 32 (25.0) (11.5, 43.4)	27/ 52 (51.9) (37.6, 66.0)	4.01 (1.34, 12.81) 0.006	2.24 (1.19, 4.21) 0.012	0.32 (0.11, 0.52) 0.002	
Europe	15/ 35 (42.9) (26.3, 60.6)	38/ 71 (53.5) (41.3, 65.5)	1.61 (0.66, 3.99) 0.258	1.28 (0.82, 1.98) 0.278	0.12 (-0.08, 0.32) 0.250	
Country						NA
BEL	1/ 1 (100.0) (2.5, 100.0)	0/ 2 (0.0) (0.0, 84.2)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
CAN	1/ 5 (20.0) (0.5, 71.6)	4/ 8 (50.0) (15.7, 84.3)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
CHE	0/ 1 (0.0) (0.0, 97.5)	1/ 2 (50.0) (1.3, 98.7)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
DEU	8/ 14 (57.1) (28.9, 82.3)	5/ 17 (29.4) (10.3, 56.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	

Abbreviations: PGIS = Patients Global Impression of Symptom Severity, CI = Confidence Interval
PGIS: 0=Absent, 1=Minimal, 2=Moderate, 3=Severe, 4=Very Severe
Note: Patient reached C7D1 or EOS prior to C7D1 with missing C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.6.3.2a
Proportion of Patients with PGIS Change from Baseline <= -1 at C7D1
Per Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with PGIS Change from Baseline <= -1 at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
DNK	0/0	1/ 1 (100.0)	NA	NA	NA	
		(2.5, 100.0)	(NA, NA)	(NA, NA)	(NA, NA)	
			NA	NA	NA	
ESP	2/ 3 (66.7)	9/ 13 (69.2)	NA	NA	NA	
	(9.4, 99.2)	(38.6, 90.9)	(NA, NA)	(NA, NA)	(NA, NA)	
			NA	NA	NA	
FRA	2/ 5 (40.0)	7/ 10 (70.0)	NA	NA	NA	
	(5.3, 85.3)	(34.8, 93.3)	(NA, NA)	(NA, NA)	(NA, NA)	
			NA	NA	NA	
GBR	1/ 5 (20.0)	6/ 10 (60.0)	NA	NA	NA	
	(0.5, 71.6)	(26.2, 87.8)	(NA, NA)	(NA, NA)	(NA, NA)	
			NA	NA	NA	
ITA	0/0	1/ 3 (33.3)	NA	NA	NA	
		(0.8, 90.6)	(NA, NA)	(NA, NA)	(NA, NA)	
			NA	NA	NA	
NLD	0/ 3 (0.0)	4/ 7 (57.1)	NA	NA	NA	
	(0.0, 70.8)	(18.4, 90.1)	(NA, NA)	(NA, NA)	(NA, NA)	
			NA	NA	NA	
NOR	1/ 2 (50.0)	3/ 5 (60.0)	NA	NA	NA	
	(1.3, 98.7)	(14.7, 94.7)	(NA, NA)	(NA, NA)	(NA, NA)	
			NA	NA	NA	

Abbreviations: PGIS = Patients Global Impression of Symptom Severity, CI = Confidence Interval
PGIS: 0=Absent, 1=Minimal, 2=Moderate, 3=Severe, 4=Very Severe
Note: Patient reached C7D1 or EOS prior to C7D1 with missing C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.6.3.2a
Proportion of Patients with PGIS Change from Baseline <= -1 at C7D1
Per Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with PGIS Change from Baseline <= -1 at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
SWE	0/ 1 (0.0) (0.0, 97.5)	1/ 1 (100.0) (2.5, 100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
USA	7/ 27 (25.9) (11.1, 46.3)	23/ 44 (52.3) (36.7, 67.5)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
Baseline ISM Status						0.654
Moderate	7/ 22 (31.8) (13.9, 54.9)	19/ 37 (51.4) (34.4, 68.1)	3.84 (0.98, 15.21) 0.030	1.95 (1.01, 3.77) 0.048	0.29 (0.05, 0.53) 0.017	
Severe	16/ 45 (35.6) (21.9, 51.2)	46/ 86 (53.5) (42.4, 64.3)	2.03 (0.91, 4.60) 0.061	1.49 (0.95, 2.32) 0.081	0.17 (-0.00, 0.35) 0.054	
Baseline Serum Tryptase (ng/mL)						0.156
< 20	4/ 13 (30.8) (9.1, 61.4)	7/ 26 (26.9) (11.6, 47.8)	1.16 (0.20, 7.43) 0.854	1.10 (0.40, 3.04) 0.852	0.03 (-0.27, 0.33) 0.848	
>= 20	19/ 54 (35.2) (22.7, 49.4)	58/ 97 (59.8) (49.3, 69.6)	2.80 (1.32, 5.95) 0.003	1.71 (1.15, 2.55) 0.008	0.25 (0.09, 0.41) 0.002	

Abbreviations: PGIS = Patients Global Impression of Symptom Severity, CI = Confidence Interval
PGIS: 0=Absent, 1=Minimal, 2=Moderate, 3=Severe, 4=Very Severe
Note: Patient reached C7D1 or EOS prior to C7D1 with missing C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.6.3.2a
Proportion of Patients with PGIS Change from Baseline <= -1 at C7D1
Per Protocol Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with PGIS Change from Baseline <= -1 at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
ECOG Status						0.412
0 or 1	21/ 63 (33.3) (22.0, 46.3)	61/114 (53.5) (43.9, 62.9)	2.61 (1.29, 5.32) 0.004	1.69 (1.15, 2.48) 0.008	0.23 (0.08, 0.37) 0.002	
2+	2/ 4 (50.0) (6.8, 93.2)	4/ 9 (44.4) (13.7, 78.8)	1.00 (0.05, 19.44) >0.999	1.00 (0.29, 3.45) >0.999	0.00 (-0.62, 0.62) >0.999	
Prior TKI therapy						0.631
Yes	1/ 3 (33.3) (0.8, 90.6)	7/ 10 (70.0) (34.8, 93.3)	NE (0.27, NE) 0.156	2.92 (0.39, 21.83) 0.297	0.47 (0.06, 0.88) 0.026	
No	22/ 64 (34.4) (22.9, 47.3)	58/113 (51.3) (41.7, 60.8)	2.26 (1.13, 4.57) 0.013	1.57 (1.07, 2.30) 0.020	0.19 (0.05, 0.34) 0.010	

Abbreviations: PGIS = Patients Global Impression of Symptom Severity, CI = Confidence Interval
PGIS: 0=Absent, 1=Minimal, 2=Moderate, 3=Severe, 4=Very Severe
Note: Patient reached C7D1 or EOS prior to C7D1 with missing C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

Table 35.1.4.4.2a
Proportion of Patients with BSC Decrease or Completely Discontinued at C7D1
Per Protocol Population, Part 2 (Part 2 Baseline)

Patients with BSC Decrease / Discontinued at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Overall	8/ 67 (11.9) (5.3, 22.2)	29/123 (23.6) (16.4, 32.1)	2.22 (0.90, 6.01) 0.063	1.92 (0.94, 3.94) 0.074	0.11 (0.00, 0.22) 0.043	
Age Group (Years)						0.124
< 65	7/ 56 (12.5) (5.2, 24.1)	25/117 (21.4) (14.3, 29.9)	1.89 (0.72, 5.51) 0.169	1.70 (0.78, 3.73) 0.182	0.09 (-0.03, 0.20) 0.134	
>= 65	1/ 11 (9.1) (0.2, 41.3)	4/ 6 (66.7) (22.3, 95.7)	8.00 (0.16, 586.99) 0.217	2.40 (0.46, 12.61) 0.301	0.32 (-0.20, 0.84) 0.233	
Sex						0.523
Male	1/ 15 (6.7) (0.2, 31.9)	8/ 35 (22.9) (10.4, 40.1)	4.98 (0.51, 227.45) 0.138	3.78 (0.51, 27.90) 0.192	0.18 (-0.01, 0.37) 0.060	
Female	7/ 52 (13.5) (5.6, 25.8)	21/ 88 (23.9) (15.4, 34.1)	1.80 (0.67, 5.51) 0.209	1.62 (0.75, 3.48) 0.218	0.09 (-0.04, 0.22) 0.188	

Abbreviations: BSC = Best Supportive Care.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

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Table 35.1.4.4.2a
Proportion of Patients with BSC Decrease or Completely Discontinued at C7D1
Per Protocol Population, Part 2 (Part 2 Baseline)

Patients with BSC Decrease / Discontinued at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Region						0.651
North America	3/ 32 (9.4) (2.0, 25.0)	12/ 52 (23.1) (12.5, 36.8)	2.95 (0.65, 16.79) 0.130	2.60 (0.69, 9.82) 0.159	0.14 (-0.02, 0.29) 0.088	
Europe	5/ 35 (14.3) (4.8, 30.3)	17/ 71 (23.9) (14.6, 35.5)	1.88 (0.58, 7.13) 0.258	1.66 (0.67, 4.11) 0.270	0.10 (-0.06, 0.25) 0.221	
Country						0.998
BEL	0/ 1 (0.0) (0.0, 97.5)	0/ 2 (0.0) (0.0, 84.2)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
CAN	1/ 5 (20.0) (0.5, 71.6)	3/ 8 (37.5) (8.5, 75.5)	0.67 (0.01, 58.83) 0.808	0.67 (0.02, 21.81) >0.999	-0.08 (-0.68, 0.52) 0.794	
CHE	0/ 1 (0.0) (0.0, 97.5)	1/ 2 (50.0) (1.3, 98.7)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
DEU	1/ 14 (7.1) (0.2, 33.9)	2/ 17 (11.8) (1.5, 36.4)	1.61 (0.08, 100.45) 0.700	1.55 (0.17, 13.99) 0.696	0.04 (-0.17, 0.26) 0.693	
DNK	0/0	0/ 1 (0.0) (0.0, 97.5)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	

Abbreviations: BSC = Best Supportive Care.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

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Table 35.1.4.4.2a
Proportion of Patients with BSC Decrease or Completely Discontinued at C7D1
Per Protocol Population, Part 2 (Part 2 Baseline)

Patients with BSC Decrease / Discontinued at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
ESP	0/ 3 (0.0) (0.0, 70.8)	4/ 13 (30.8) (9.1, 61.4)	NE (0.23, NE) 0.245	NE (NE, NE) NE	0.38 (0.07, 0.68) 0.014	
FRA	1/ 5 (20.0) (0.5, 71.6)	1/ 10 (10.0) (0.3, 44.5)	0.00 (0.00, 6.33) 0.083	0.00 (NE, NE) NE	-0.25 (-0.62, 0.12) 0.190	
GBR	2/ 5 (40.0) (5.3, 85.3)	4/ 10 (40.0) (12.2, 73.8)	2.06 (0.12, 42.36) 0.599	1.42 (0.39, 5.15) 0.589	0.16 (-0.36, 0.68) 0.550	
ITA	0/0	1/ 3 (33.3) (0.8, 90.6)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
NLD	1/ 3 (33.3) (0.8, 90.6)	2/ 7 (28.6) (3.7, 71.0)	4.00 (0.07, 352.00) 0.456	2.00 (0.33, 11.97) 0.448	0.33 (-0.42, 1.00) 0.386	
NOR	0/ 2 (0.0) (0.0, 84.2)	2/ 5 (40.0) (5.3, 85.3)	NE (0.12, NE) 0.362	NE (NE, NE) NE	0.41 (-0.02, 0.84) 0.061	

Abbreviations: BSC = Best Supportive Care.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

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Table 35.1.4.4.2a
Proportion of Patients with BSC Decrease or Completely Discontinued at C7D1
Per Protocol Population, Part 2 (Part 2 Baseline)

Patients with BSC Decrease / Discontinued at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
SWE	0/ 1 (0.0) (0.0, 97.5)	0/ 1 (0.0) (0.0, 97.5)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
USA	2/ 27 (7.4) (0.9, 24.3)	9/ 44 (20.5) (9.8, 35.3)	3.47 (0.59, 34.19) 0.136	2.85 (0.65, 12.47) 0.164	0.14 (-0.02, 0.29) 0.090	
Baseline ISM Status						0.195
Moderate	1/ 22 (4.5) (0.1, 22.8)	9/ 37 (24.3) (11.8, 41.2)	7.43 (0.82, 332.74) 0.048	5.77 (0.74, 44.85) 0.094	0.21 (0.04, 0.38) 0.016	
Severe	7/ 45 (15.6) (6.5, 29.5)	20/ 86 (23.3) (14.8, 33.6)	1.59 (0.57, 4.86) 0.344	1.45 (0.66, 3.15) 0.352	0.07 (-0.07, 0.21) 0.318	
Baseline Serum Tryptase (ng/mL)						0.999
< 20	1/ 13 (7.7) (0.2, 36.0)	4/ 26 (15.4) (4.4, 34.9)	2.07 (0.16, 110.20) 0.563	1.94 (0.20, 19.11) 0.571	0.07 (-0.13, 0.27) 0.511	
>= 20	7/ 54 (13.0) (5.4, 24.9)	25/ 97 (25.8) (17.4, 35.7)	2.24 (0.86, 6.67) 0.077	1.92 (0.90, 4.08) 0.090	0.12 (-0.00, 0.25) 0.056	

Abbreviations: BSC = Best Supportive Care.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

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Table 35.1.4.4.2a
Proportion of Patients with BSC Decrease or Completely Discontinued at C7D1
Per Protocol Population, Part 2 (Part 2 Baseline)

Patients with BSC Decrease / Discontinued at C7D1	Placebo (N=67) n/N (%) (95% CIs)	Avapritinib 25 mg (N=123) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
ECOG Status						0.968
0 or 1	8/ 63 (12.7) (5.6, 23.5)	25/114 (21.9) (14.7, 30.6)	1.87 (0.74, 5.14) 0.159	1.67 (0.80, 3.47) 0.171	0.09 (-0.03, 0.20) 0.133	
2+	0/ 4 (0.0) (0.0, 60.2)	4/ 9 (44.4) (13.7, 78.8)	NE (0.29, NE) 0.186	NE (NE, NE) NE	0.40 (0.05, 0.75) 0.025	
Prior TKI therapy						0.115
Yes	1/ 3 (33.3) (0.8, 90.6)	1/ 10 (10.0) (0.3, 44.5)	0.19 (0.00, 25.18) 0.347	0.19 (0.00, 9.35) >0.999	-0.27 (-0.87, 0.34) 0.391	
No	7/ 64 (10.9) (4.5, 21.2)	28/113 (24.8) (17.1, 33.8)	2.65 (1.02, 7.68) 0.030	2.21 (1.04, 4.70) 0.040	0.14 (0.02, 0.25) 0.017	

Abbreviations: BSC = Best Supportive Care.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

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Table 35.2.11.4.2.1a
Summary of Mastocytosis in Skin by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	27	60	8	4	
Mean (StdDev)	15.7 (27.49)	7.8 (16.46)	36.6 (38.44)	23.8 (38.35)	
Median	2.0	2.0	18.0	6.0	
Min, Max	0, 92	0, 91	0, 91	2, 81	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
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Table 35.2.11.4.2.1a
Summary of Mastocytosis in Skin by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	20	43	5	4	
Mean (StdDev)	19.0 (33.00)	5.4 (11.85)	34.2 (38.38)	22.8 (42.20)	
Median	3.0	2.0	18.0	2.5	
Min, Max	0, 97	0, 61	1, 78	0, 86	
C4D1 CFB					
n	20	43	5	4	
LS Mean (StdErr) [2]	1.34 (0.848)	-1.61 (0.611)	-2.33 (4.293)	-2.67 (6.853)	
95% CI [2]	-0.36, 3.03	-2.83, -0.39	-13.37, 8.70	-20.28, 14.95	
Difference (95% CI) in CFB [2]		-2.95 (-4.79, -1.10)		-0.33 (-16.19, 15.52)	
p-value [3]		0.002		0.959	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
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Table 35.2.11.4.2.1a
Summary of Mastocytosis in Skin by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	15	45	4	3	
Mean (StdDev)	18.7 (34.78)	6.1 (13.89)	30.5 (42.40)	28.7 (47.06)	
Median	1.0	1.0	14.0	2.0	
Min, Max	0, 98	0, 81	1, 93	1, 83	
C7D1 CFB					
n	15	45	4	3	
LS Mean (StdErr) [2]	1.27 (1.924)	-2.76 (1.191)	1.00 (2.614)	-0.33 (5.579)	
95% CI [2]	-2.59, 5.12	-5.15, -0.38	-7.32, 9.32	-18.09, 17.42	
Difference (95% CI) in CFB [2]		-4.03 (-8.17, 0.12)		-1.33 (-17.02, 14.35)	
Hedges'G (95% CI) in CFB		-0.51 (-1.13, 0.08)		-0.15 (-2.21, 1.72)	
p-value [3]		0.057		0.804	
					0.746

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
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Table 35.2.11.4.2.1a
Summary of Mastocytosis in Skin by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	27	60	8	4	
Mean (StdDev)	11.9 (23.57)	7.1 (16.06)	31.0 (33.56)	6.5 (7.33)	
Median	1.0	2.0	15.5	4.0	
Min, Max	0, 89	0, 91	1, 91	1, 17	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
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Table 35.2.11.4.2.1a
Summary of Mastocytosis in Skin by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	20	43	5	4	
Mean (StdDev)	14.1 (26.25)	4.7 (10.69)	34.0 (39.30)	12.0 (22.67)	
Median	2.0	2.0	15.0	1.0	
Min, Max	0, 85	0, 56	0, 80	0, 46	
C4D1 CFB					
n	20	43	5	4	
LS Mean (StdErr) [2]	0.48 (0.862)	-1.63 (0.621)	-1.17 (8.555)	-9.83 (13.658)	
95% CI [2]	-1.24, 2.20	-2.88, -0.39	-23.16, 20.83	-44.94, 25.27	
Difference (95% CI) in CFB [2]		-2.11 (-3.99, -0.24)		-8.67 (-40.27, 22.93)	
p-value [3]		0.028		0.512	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
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Table 35.2.11.4.2.1a
Summary of Mastocytosis in Skin by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	15	45	4	3	
Mean (StdDev)	13.5 (25.25)	5.0 (12.80)	30.3 (42.34)	8.3 (13.58)	
Median	2.0	2.0	13.5	1.0	
Min, Max	0, 79	0, 81	1, 93	0, 24	
C7D1 CFB					
n	15	45	4	3	
LS Mean (StdErr) [2]	-0.63 (2.392)	-2.36 (1.480)	0.75 (3.065)	0.08 (6.542)	
95% CI [2]	-5.42, 4.17	-5.33, 0.60	-9.01, 10.51	-20.74, 20.90	
Difference (95% CI) in CFB [2]		-1.74 (-6.89, 3.41)		-0.67 (-19.06, 17.73)	
Hedges'G (95% CI) in CFB		-0.18 (-0.78, 0.42)		-0.07 (-2.07, 1.86)	
p-value [3]		0.502		0.915	
					0.702

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-age-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.2.1a
Summary of Mastocytosis in Skin by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	27	59	8	4	
Mean (StdDev)	9.8 (21.86)	6.0 (16.18)	32.3 (35.12)	21.5 (39.68)	
Median	1.0	1.0	18.0	2.0	
Min, Max	0, 92	0, 99	0, 86	1, 81	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-age-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.2.1a
Summary of Mastocytosis in Skin by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	20	42	5	4	
Mean (StdDev)	10.7 (26.01)	2.2 (4.69)	30.0 (38.46)	21.8 (42.84)	
Median	1.0	1.0	18.0	0.5	
Min, Max	0, 97	0, 28	0, 93	0, 86	
C4D1 CFB					
n	20	42	5	4	
LS Mean (StdErr) [2]	1.10 (2.105)	-2.04 (1.528)	-0.54 (1.916)	-3.21 (3.058)	
95% CI [2]	-3.11, 5.31	-5.10, 1.02	-5.47, 4.38	-11.07, 4.65	
Difference (95% CI) in CFB [2]		-3.14 (-7.73, 1.44)		-2.67 (-9.74, 4.41)	
p-value [3]		0.175		0.377	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-age-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.2.1a
Summary of Mastocytosis in Skin by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	15	45	4	3	
Mean (StdDev)	13.1 (29.59)	3.9 (11.79)	14.5 (13.20)	28.0 (47.63)	
Median	1.0	1.0	14.0	1.0	
Min, Max	0, 98	0, 73	0, 30	0, 83	
C7D1 CFB					
n	15	45	4	3	
LS Mean (StdErr) [2]	0.45 (2.849)	-2.89 (1.763)	-3.00 (3.175)	-2.33 (6.778)	
95% CI [2]	-5.26, 6.15	-6.42, 0.64	-13.11, 7.11	-23.90, 19.24	
Difference (95% CI) in CFB [2]		-3.34 (-9.47, 2.80)		0.67 (-18.39, 19.72)	
Hedges'G (95% CI) in CFB		-0.28 (-0.89, 0.31)		0.06 (-1.86, 2.06)	
p-value [3]		0.280		0.918	
					0.409

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-age-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.2.1a
Summary of Mastocytosis in Skin by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	27	60	8	4	
Mean (StdDev)	14.6 (26.13)	7.7 (16.03)	34.3 (35.14)	13.0 (17.09)	
Median	2.0	3.0	16.0	6.0	
Min, Max	0, 88	0, 86	1, 82	2, 38	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-age-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.2.1a
Summary of Mastocytosis in Skin by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	20	43	5	4	
Mean (StdDev)	16.8 (28.40)	5.6 (11.78)	32.6 (36.04)	12.0 (20.74)	
Median	3.0	2.0	18.0	2.5	
Min, Max	0, 75	0, 61	1, 78	0, 43	
C4D1 CFB					
n	20	43	5	4	
LS Mean (StdErr) [2]	-0.13 (1.130)	-1.29 (0.814)	-0.73 (2.872)	-2.90 (4.585)	
95% CI [2]	-2.39, 2.13	-2.92, 0.34	-8.11, 6.65	-14.68, 8.89	
Difference (95% CI) in CFB [2]		-1.17 (-3.63, 1.30)		-2.17 (-12.77, 8.44)	
p-value [3]		0.347		0.622	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-age-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.2.1a
Summary of Mastocytosis in Skin by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	15	45	4	3	
Mean (StdDev)	14.9 (29.41)	6.4 (14.73)	27.3 (33.42)	12.3 (18.77)	
Median	1.0	1.0	16.0	2.0	
Min, Max	0, 91	0, 87	1, 76	1, 34	
C7D1 CFB					
n	15	45	4	3	
LS Mean (StdErr) [2]	-1.43 (2.958)	-1.64 (1.830)	1.25 (1.774)	-4.08 (3.786)	
95% CI [2]	-7.36, 4.49	-5.31, 2.02	-4.39, 6.89	-16.13, 7.96	
Difference (95% CI) in CFB [2]		-0.21 (-6.58, 6.16)		-5.33 (-15.98, 5.31)	
Hedges'G (95% CI) in CFB		-0.02 (-0.61, 0.58)		-0.90 (-3.55, 0.68)	
p-value [3]		0.948		0.209	
					0.618

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-age-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.2.1a
Summary of Mastocytosis in Skin by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	27	60	8	4	
Mean (StdDev)	6.9 (14.41)	4.9 (11.99)	29.0 (33.01)	21.0 (36.71)	
Median	1.0	1.0	17.5	3.5	
Min, Max	0, 57	0, 84	0, 84	1, 76	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-age-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.2.1a
Summary of Mastocytosis in Skin by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	20	43	5	4	
Mean (StdDev)	9.3 (21.26)	2.3 (4.44)	28.8 (36.53)	15.0 (28.67)	
Median	1.0	1.0	22.0	1.0	
Min, Max	0, 83	0, 27	1, 90	0, 58	
C4D1 CFB					
n	20	43	5	4	
LS Mean (StdErr) [2]	1.82 (1.308)	-1.57 (0.943)	1.44 (3.824)	-6.06 (6.104)	
95% CI [2]	-0.80, 4.44	-3.46, 0.31	-8.39, 11.27	-21.75, 9.63	
Difference (95% CI) in CFB [2]		-3.39 (-6.25, -0.54)		-7.50 (-21.62, 6.62)	
p-value [3]		0.020		0.230	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-age-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.2.1a
Summary of Mastocytosis in Skin by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	15	45	4	3	
Mean (StdDev)	10.3 (22.42)	3.0 (8.51)	16.0 (15.19)	22.3 (36.95)	
Median	1.0	1.0	14.0	1.0	
Min, Max	0, 65	0, 53	1, 35	1, 65	
C7D1 CFB					
n	15	45	4	3	
LS Mean (StdErr) [2]	1.38 (1.660)	-3.05 (1.027)	1.75 (3.413)	-2.58 (7.284)	
95% CI [2]	-1.95, 4.71	-5.11, -0.99	-9.11, 12.61	-25.76, 20.60	
Difference (95% CI) in CFB [2]		-4.43 (-8.00, -0.85)		-4.33 (-24.81, 16.15)	
Hedges'G (95% CI) in CFB		-0.64 (-1.28, -0.06)		-0.38 (-2.60, 1.38)	
p-value [3]		0.016		0.549	
					0.714

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-age-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.2.2a
Summary of Mastocytosis in Skin by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	8	17	27	47	
Mean (StdDev)	26.5 (35.53)	9.6 (19.06)	18.7 (30.06)	8.5 (18.37)	
Median	5.0	4.0	2.0	2.0	
Min, Max	2, 92	0, 81	0, 91	0, 91	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-sex-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.2.2a
Summary of Mastocytosis in Skin by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	7	12	18	35	
Mean (StdDev)	27.0 (40.87)	9.6 (24.20)	20.1 (31.85)	5.9 (13.04)	
Median	3.0	2.0	2.0	2.0	
Min, Max	0, 97	0, 86	0, 85	0, 61	
C4D1 CFB					
n	7	12	18	35	
LS Mean (StdErr) [2]	1.17 (1.248)	-1.36 (1.057)	-0.16 (1.147)	-1.74 (0.897)	
95% CI [2]	-1.49, 3.83	-3.62, 0.89	-2.46, 2.14	-3.54, 0.06	
Difference (95% CI) in CFB [2]		-2.53 (-5.64, 0.57)		-1.58 (-4.10, 0.93)	
p-value [3]		0.103		0.212	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-sex-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.2.2a
Summary of Mastocytosis in Skin by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	5	12	14	36	
Mean (StdDev)	37.6 (47.00)	10.9 (22.97)	15.4 (30.52)	6.4 (15.46)	
Median	7.0	4.5	1.0	1.0	
Min, Max	1, 98	0, 83	0, 93	0, 81	
C7D1 CFB					
n	5	12	14	36	
LS Mean (StdErr) [2]	2.35 (2.332)	-2.59 (1.647)	0.53 (2.033)	-2.75 (1.412)	
95% CI [2]	-2.69, 7.38	-6.15, 0.97	-3.56, 4.62	-5.59, 0.09	
Difference (95% CI) in CFB [2]		-4.93 (-10.30, 0.43)		-3.28 (-7.83, 1.27)	
Hedges'G (95% CI) in CFB		-0.84 (-2.16, 0.21)		-0.39 (-1.05, 0.23)	
p-value [3]		0.068		0.153	
					0.654

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-sex-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.2.2a
Summary of Mastocytosis in Skin by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	8	17	27	47	
Mean (StdDev)	18.6 (31.08)	5.6 (4.99)	15.6 (26.13)	7.6 (18.02)	
Median	3.5	4.0	1.0	1.0	
Min, Max	1, 89	0, 17	0, 91	0, 91	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-sex-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.2.2a
Summary of Mastocytosis in Skin by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	7	12	18	35	
Mean (StdDev)	18.4 (30.04)	5.8 (12.89)	17.9 (30.14)	5.1 (11.77)	
Median	3.0	2.0	2.0	1.0	
Min, Max	1, 79	0, 46	0, 85	0, 56	
C4D1 CFB					
n	7	12	18	35	
LS Mean (StdErr) [2]	-1.91 (3.379)	-0.02 (2.862)	0.89 (1.583)	-2.00 (1.239)	
95% CI [2]	-9.11, 5.29	-6.12, 6.08	-2.29, 4.07	-4.49, 0.48	
Difference (95% CI) in CFB [2]		1.88 (-6.53, 10.30)		-2.89 (-6.36, 0.58)	
p-value [3]		0.640		0.100	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-sex-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.2.2a
Summary of Mastocytosis in Skin by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	5	12	14	36	
Mean (StdDev)	22.0 (27.09)	5.0 (6.52)	15.2 (30.49)	5.2 (14.29)	
Median	4.0	3.0	1.5	1.0	
Min, Max	1, 59	0, 24	0, 93	0, 81	
C7D1 CFB					
n	5	12	14	36	
LS Mean (StdErr) [2]	-3.44 (4.405)	-1.07 (3.112)	0.77 (2.368)	-2.57 (1.644)	
95% CI [2]	-12.96, 6.07	-7.79, 5.65	-3.99, 5.54	-5.88, 0.74	
Difference (95% CI) in CFB [2]		2.37 (-7.76, 12.50)		-3.34 (-8.64, 1.95)	
Hedges'G (95% CI) in CFB		0.21 (-0.89, 1.39)		-0.34 (-1.00, 0.28)	
p-value [3]		0.622		0.210	
					0.285

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-sex-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.2.2a
Summary of Mastocytosis in Skin by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	8	17	27	46	
Mean (StdDev)	24.9 (35.43)	8.1 (19.19)	12.0 (23.50)	6.6 (18.19)	
Median	2.5	2.0	1.0	1.0	
Min, Max	1, 92	0, 81	0, 86	0, 99	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-sex-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.2.2a
Summary of Mastocytosis in Skin by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	7	12	18	34	
Mean (StdDev)	25.0 (41.01)	8.3 (24.49)	10.4 (23.16)	2.4 (5.18)	
Median	2.0	1.0	1.0	1.0	
Min, Max	0, 97	0, 86	0, 93	0, 28	
C4D1 CFB					
n	7	12	18	34	
LS Mean (StdErr) [2]	0.73 (1.197)	-1.28 (1.014)	0.63 (2.402)	-2.19 (1.900)	
95% CI [2]	-1.82, 3.29	-3.44, 0.88	-4.20, 5.46	-6.01, 1.63	
Difference (95% CI) in CFB [2]		-2.02 (-5.00, 0.97)		-2.82 (-8.10, 2.46)	
p-value [3]		0.170		0.288	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-sex-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.2.2a
Summary of Mastocytosis in Skin by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	5	12	14	36	
Mean (StdDev)	34.6 (46.18)	9.7 (23.26)	5.9 (9.68)	4.0 (13.15)	
Median	3.0	2.0	1.0	1.0	
Min, Max	1, 98	0, 83	0, 30	0, 73	
C7D1 CFB					
n	5	12	14	36	
LS Mean (StdErr) [2]	1.49 (1.635)	-1.94 (1.155)	-1.40 (3.167)	-3.04 (2.199)	
95% CI [2]	-2.05, 5.02	-4.43, 0.56	-7.78, 4.97	-7.47, 1.38	
Difference (95% CI) in CFB [2]		-3.42 (-7.18, 0.34)		-1.64 (-8.72, 5.44)	
Hedges'G (95% CI) in CFB		-0.83 (-2.15, 0.22)		-0.13 (-0.77, 0.50)	
p-value [3]		0.071		0.643	
					0.731

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-sex-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.2.2a
Summary of Mastocytosis in Skin by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	8	17	27	47	
Mean (StdDev)	24.1 (34.40)	7.3 (9.18)	17.6 (27.90)	8.2 (17.93)	
Median	5.0	5.0	2.0	2.0	
Min, Max	2, 88	0, 38	0, 82	0, 86	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-sex-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.2.2a
Summary of Mastocytosis in Skin by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	7	12	18	35	
Mean (StdDev)	22.7 (32.49)	6.5 (11.62)	18.8 (29.82)	6.1 (13.04)	
Median	3.0	4.0	2.0	2.0	
Min, Max	2, 75	0, 43	0, 78	0, 61	
C4D1 CFB					
n	7	12	18	35	
LS Mean (StdErr) [2]	-2.05 (2.681)	-0.93 (2.271)	0.33 (0.981)	-1.38 (0.768)	
95% CI [2]	-7.76, 3.67	-5.77, 3.91	-1.65, 2.30	-2.93, 0.16	
Difference (95% CI) in CFB [2]		1.12 (-5.56, 7.79)		-1.71 (-3.86, 0.44)	
p-value [3]		0.726		0.117	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-sex-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.2.2a
Summary of Mastocytosis in Skin by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	5	12	14	36	
Mean (StdDev)	23.6 (32.78)	7.6 (9.61)	15.3 (29.60)	6.5 (16.32)	
Median	7.0	5.0	1.0	1.0	
Min, Max	1, 79	0, 34	0, 91	0, 87	
C7D1 CFB					
n	5	12	14	36	
LS Mean (StdErr) [2]	-8.13 (8.085)	-0.01 (5.712)	1.98 (2.114)	-2.40 (1.468)	
95% CI [2]	-25.59, 9.34	-12.35, 12.33	-2.27, 6.24	-5.36, 0.55	
Difference (95% CI) in CFB [2]		8.11 (-10.49, 26.71)		-4.39 (-9.12, 0.34)	
Hedges'G (95% CI) in CFB		0.40 (-0.68, 1.61)		-0.50 (-1.17, 0.11)	
p-value [3]		0.363		0.068	
					0.038

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-sex-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.2.2a
Summary of Mastocytosis in Skin by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	8	17	27	47	
Mean (StdDev)	15.9 (23.80)	7.2 (18.26)	10.7 (21.42)	5.4 (13.28)	
Median	1.5	2.0	1.0	1.0	
Min, Max	0, 57	0, 76	0, 84	0, 84	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-sex-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.2.2a
Summary of Mastocytosis in Skin by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	7	12	18	35	
Mean (StdDev)	19.9 (33.76)	5.7 (16.50)	10.6 (21.94)	2.6 (4.87)	
Median	1.0	1.0	1.5	1.0	
Min, Max	0, 83	0, 58	0, 90	0, 27	
C4D1 CFB					
n	7	12	18	35	
LS Mean (StdErr) [2]	3.50 (3.121)	-2.95 (2.644)	1.22 (1.166)	-1.49 (0.912)	
95% CI [2]	-3.15, 10.16	-8.59, 2.69	-1.13, 3.56	-3.33, 0.34	
Difference (95% CI) in CFB [2]		-6.45 (-14.23, 1.32)		-2.71 (-5.27, -0.15)	
p-value [3]		0.097		0.038	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-sex-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.2.2a
Summary of Mastocytosis in Skin by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	5	12	14	36	
Mean (StdDev)	26.2 (34.97)	7.3 (18.48)	6.2 (10.64)	3.2 (9.36)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 65	0, 65	0, 35	0, 53	
C7D1 CFB					
n	5	12	14	36	
LS Mean (StdErr) [2]	4.47 (2.415)	-2.85 (1.706)	0.32 (1.739)	-3.07 (1.208)	
95% CI [2]	-0.75, 9.68	-6.54, 0.83	-3.18, 3.82	-5.50, -0.63	
Difference (95% CI) in CFB [2]		-7.32 (-12.88, -1.77)		-3.39 (-7.28, 0.50)	
Hedges'G (95% CI) in CFB		-1.20 (-2.62, -0.16)		-0.47 (-1.14, 0.15)	
p-value [3]		0.014		0.086	
					0.258

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-sex-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.2.3a
Summary of Mastocytosis in Skin by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	13	21	22	43	
Mean (StdDev)	19.8 (28.34)	11.5 (25.04)	20.9 (33.14)	7.5 (14.30)	
Median	7.0	3.0	2.0	2.0	
Min, Max	0, 91	0, 91	0, 92	0, 81	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-reg-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.2.3a
Summary of Mastocytosis in Skin by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	6	13	19	34	
Mean (StdDev)	26.3 (36.21)	6.5 (16.44)	20.6 (34.00)	7.0 (16.61)	
Median	5.0	2.0	3.0	2.0	
Min, Max	1, 73	0, 61	0, 97	0, 86	
C4D1 CFB					
n	6	13	19	34	
LS Mean (StdErr) [2]	-1.76 (3.171)	-1.89 (2.804)	0.74 (0.611)	-1.41 (0.474)	
95% CI [2]	-8.52, 5.00	-7.87, 4.08	-0.49, 1.96	-2.36, -0.46	
Difference (95% CI) in CFB [2]		-0.13 (-8.05, 7.78)		-2.15 (-3.50, -0.79)	
p-value [3]		0.972		0.003	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-reg-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.2.3a
Summary of Mastocytosis in Skin by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	5	13	14	35	
Mean (StdDev)	21.8 (39.96)	10.5 (22.84)	21.0 (35.50)	6.4 (15.27)	
Median	7.0	2.0	1.5	1.0	
Min, Max	0, 93	0, 81	0, 98	0, 83	
C7D1 CFB					
n	5	13	14	35	
LS Mean (StdErr) [2]	1.35 (5.875)	-3.93 (4.260)	0.76 (0.854)	-2.08 (0.580)	
95% CI [2]	-11.25, 13.95	-13.06, 5.21	-0.96, 2.47	-3.25, -0.91	
Difference (95% CI) in CFB [2]		-5.28 (-19.24, 8.69)		-2.83 (-4.73, -0.94)	
Hedges'G (95% CI) in CFB		-0.34 (-1.51, 0.73)		-0.83 (-1.53, -0.21)	
p-value [3]		0.431		0.004	
					0.464

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-reg-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.2.3a
Summary of Mastocytosis in Skin by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	13	21	22	43	
Mean (StdDev)	15.4 (25.14)	11.1 (24.27)	16.8 (28.42)	5.1 (8.59)	
Median	7.0	3.0	1.0	2.0	
Min, Max	0, 91	0, 91	0, 89	0, 49	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-reg-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.2.3a
Summary of Mastocytosis in Skin by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	6	13	19	34	
Mean (StdDev)	21.2 (30.41)	5.8 (15.16)	17.1 (29.96)	5.1 (10.70)	
Median	4.5	1.0	2.0	1.5	
Min, Max	0, 73	0, 56	0, 85	0, 46	
C4D1 CFB					
n	6	13	19	34	
LS Mean (StdErr) [2]	-2.26 (3.118)	-2.82 (2.756)	0.64 (1.659)	-1.02 (1.288)	
95% CI [2]	-8.91, 4.38	-8.69, 3.06	-2.69, 3.97	-3.61, 1.57	
Difference (95% CI) in CFB [2]		-0.56 (-8.34, 7.23)		-1.66 (-5.35, 2.03)	
p-value [3]		0.881		0.370	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-reg-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.2.3a
Summary of Mastocytosis in Skin by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	5	13	14	35	
Mean (StdDev)	22.0 (39.89)	9.2 (22.30)	15.2 (25.80)	3.7 (6.33)	
Median	6.0	1.0	2.0	2.0	
Min, Max	0, 93	0, 81	0, 79	0, 27	
C7D1 CFB					
n	5	13	14	35	
LS Mean (StdErr) [2]	1.54 (6.484)	-4.60 (4.702)	-1.18 (1.680)	-1.27 (1.142)	
95% CI [2]	-12.36, 15.45	-14.68, 5.48	-4.56, 2.20	-3.56, 1.03	
Difference (95% CI) in CFB [2]		-6.14 (-21.55, 9.27)		-0.08 (-3.81, 3.65)	
Hedges'G (95% CI) in CFB		-0.36 (-1.53, 0.71)		-0.01 (-0.65, 0.62)	
p-value [3]		0.407		0.964	
					0.215

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-reg-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.2.3a
Summary of Mastocytosis in Skin by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	13	20	22	43	
Mean (StdDev)	9.5 (14.16)	10.8 (26.34)	18.1 (31.75)	5.2 (13.11)	
Median	2.0	2.0	1.5	1.0	
Min, Max	0, 42	0, 99	0, 92	0, 81	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-reg-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.2.3a
Summary of Mastocytosis in Skin by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	6	12	19	34	
Mean (StdDev)	7.2 (15.13)	1.8 (2.92)	16.8 (32.23)	4.7 (15.21)	
Median	1.5	1.0	1.0	1.0	
Min, Max	0, 38	0, 11	0, 97	0, 86	
C4D1 CFB					
n	6	12	19	34	
LS Mean (StdErr) [2]	1.07 (7.272)	-3.89 (6.560)	0.31 (0.646)	-1.30 (0.502)	
95% CI [2]	-14.53, 16.67	-17.96, 10.18	-0.99, 1.61	-2.31, -0.29	
Difference (95% CI) in CFB [2]		-4.96 (-23.10, 13.18)		-1.61 (-3.05, -0.18)	
p-value [3]		0.567		0.029	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
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Table 35.2.11.4.2.3a
Summary of Mastocytosis in Skin by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	5	13	14	35	
Mean (StdDev)	8.0 (12.73)	6.5 (19.98)	15.4 (30.31)	5.0 (14.83)	
Median	2.0	1.0	1.0	1.0	
Min, Max	0, 30	0, 73	0, 98	0, 83	
C7D1 CFB					
n	5	13	14	35	
LS Mean (StdErr) [2]	-2.02 (9.112)	-7.14 (6.607)	-0.37 (0.844)	-1.12 (0.573)	
95% CI [2]	-21.56, 17.52	-21.31, 7.03	-2.07, 1.33	-2.28, 0.03	
Difference (95% CI) in CFB [2]		-5.12 (-26.78, 16.53)		-0.75 (-2.63, 1.12)	
Hedges'G (95% CI) in CFB		-0.21 (-1.36, 0.87)		-0.22 (-0.87, 0.40)	
p-value [3]		0.620		0.421	
					0.413

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
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Table 35.2.11.4.2.3a
Summary of Mastocytosis in Skin by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	13	21	22	43	
Mean (StdDev)	17.0 (24.21)	11.4 (24.24)	20.3 (32.11)	6.3 (9.81)	
Median	7.0	3.0	2.0	3.0	
Min, Max	0, 73	0, 86	0, 88	0, 47	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-reg-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.2.3a
Summary of Mastocytosis in Skin by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	6	13	19	34	
Mean (StdDev)	24.5 (34.30)	6.9 (16.38)	18.5 (29.32)	5.9 (11.06)	
Median	5.0	3.0	3.0	2.0	
Min, Max	0, 73	0, 61	0, 78	0, 50	
C4D1 CFB					
n	6	13	19	34	
LS Mean (StdErr) [2]	-0.63 (2.680)	-3.39 (2.369)	-0.35 (1.022)	-0.72 (0.794)	
95% CI [2]	-6.34, 5.08	-8.44, 1.66	-2.40, 1.71	-2.32, 0.87	
Difference (95% CI) in CFB [2]		-2.76 (-9.45, 3.94)		-0.38 (-2.65, 1.90)	
p-value [3]		0.394		0.741	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
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Table 35.2.11.4.2.3a
Summary of Mastocytosis in Skin by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	5	13	14	35	
Mean (StdDev)	19.2 (32.12)	11.0 (24.39)	16.9 (30.12)	5.2 (9.23)	
Median	7.0	2.0	1.5	1.0	
Min, Max	0, 76	0, 87	0, 91	0, 40	
C7D1 CFB					
n	5	13	14	35	
LS Mean (StdErr) [2]	2.46 (5.862)	-2.55 (4.251)	-1.90 (2.758)	-1.23 (1.874)	
95% CI [2]	-10.11, 15.04	-11.66, 6.57	-7.46, 3.65	-5.00, 2.55	
Difference (95% CI) in CFB [2]		-5.01 (-18.94, 8.92)		0.67 (-5.45, 6.79)	
Hedges'G (95% CI) in CFB		-0.32 (-1.49, 0.75)		0.06 (-0.57, 0.70)	
p-value [3]		0.453		0.826	
					0.341

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-reg-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.2.3a
Summary of Mastocytosis in Skin by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	13	21	22	43	
Mean (StdDev)	7.2 (8.57)	7.2 (18.76)	14.7 (26.47)	5.3 (12.34)	
Median	2.0	2.0	1.0	1.0	
Min, Max	0, 28	0, 84	0, 84	0, 76	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-reg-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.2.3a
Summary of Mastocytosis in Skin by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	6	13	19	34	
Mean (StdDev)	6.7 (11.71)	1.3 (1.18)	15.2 (28.32)	4.2 (10.72)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 30	0, 4	0, 90	0, 58	
C4D1 CFB					
n	6	13	19	34	
LS Mean (StdErr) [2]	1.21 (3.087)	-2.27 (2.729)	2.04 (1.195)	-1.66 (0.928)	
95% CI [2]	-5.37, 7.79	-8.08, 3.55	-0.36, 4.44	-3.52, 0.21	
Difference (95% CI) in CFB [2]		-3.47 (-11.18, 4.23)		-3.70 (-6.35, -1.04)	
p-value [3]		0.352		0.007	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
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Table 35.2.11.4.2.3a
Summary of Mastocytosis in Skin by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	5	13	14	35	
Mean (StdDev)	8.6 (15.04)	4.9 (14.48)	12.5 (22.99)	3.9 (11.44)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 35	0, 53	0, 65	0, 65	
C7D1 CFB					
n	5	13	14	35	
LS Mean (StdErr) [2]	0.27 (4.666)	-5.61 (3.384)	1.29 (0.974)	-2.04 (0.662)	
95% CI [2]	-9.74, 10.28	-12.87, 1.65	-0.67, 3.25	-3.38, -0.71	
Difference (95% CI) in CFB [2]		-5.88 (-16.97, 5.21)		-3.33 (-5.50, -1.17)	
Hedges'G (95% CI) in CFB		-0.48 (-1.68, 0.58)		-0.85 (-1.55, -0.23)	
p-value [3]		0.275		0.003	
					0.382

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.11.4.2.4a
Summary of Mastocytosis in Skin by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.11.4.2.4a
Summary of Mastocytosis in Skin by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region						
	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.11.4.2.4a
Summary of Mastocytosis in Skin by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
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Table 35.2.11.4.2.4a
Summary of Mastocytosis in Skin by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.11.4.2.4a
Summary of Mastocytosis in Skin by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region			
	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
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Table 35.2.11.4.2.4a
Summary of Mastocytosis in Skin by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-cou-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.2.4a
Summary of Mastocytosis in Skin by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.11.4.2.4a
Summary of Mastocytosis in Skin by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.11.4.2.4a
Summary of Mastocytosis in Skin by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.11.4.2.4a
Summary of Mastocytosis in Skin by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh

	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.11.4.2.4a
Summary of Mastocytosis in Skin by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-cou-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.2.4a
Summary of Mastocytosis in Skin by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-cou-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.2.4a
Summary of Mastocytosis in Skin by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-cou-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.2.4a
Summary of Mastocytosis in Skin by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.11.4.2.4a
Summary of Mastocytosis in Skin by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso

	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-cou-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.2.4a
Summary of Mastocytosis in Skin by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-cou-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.2.4a
Summary of Mastocytosis in Skin by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-cou-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.2.4a
Summary of Mastocytosis in Skin by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-cou-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.2.4a
Summary of Mastocytosis in Skin by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-cou-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.2.4a
Summary of Mastocytosis in Skin by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh

	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-cou-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.2.4a
Summary of Mastocytosis in Skin by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-cou-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.2.4a
Summary of Mastocytosis in Skin by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-cou-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.2.4a
Summary of Mastocytosis in Skin by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-cou-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.2.4a
Summary of Mastocytosis in Skin by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-cou-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.2.4a
Summary of Mastocytosis in Skin by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso			
	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-cou-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.2.5a
Summary of Mastocytosis in Skin by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	11	21	24	43	
Mean (StdDev)	22.3 (33.17)	4.7 (5.58)	19.6 (30.68)	10.8 (21.94)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 91	0, 22	0, 92	0, 91	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-ism-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.5a
Summary of Mastocytosis in Skin by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	6	17	19	30	
Mean (StdDev)	15.8 (28.84)	3.2 (4.29)	23.9 (35.79)	8.9 (20.08)	
Median	2.0	2.0	3.0	1.5	
Min, Max	0, 73	0, 17	1, 97	0, 86	
C4D1 CFB					
n	6	17	19	30	
LS Mean (StdErr) [2]	-3.04 (1.750)	-0.92 (1.176)	1.70 (0.917)	-1.75 (0.818)	
95% CI [2]	-6.69, 0.61	-3.37, 1.54	-0.15, 3.54	-3.39, -0.10	
Difference (95% CI) in CFB [2]		2.12 (-1.75, 5.99)		-3.45 (-5.68, -1.22)	
p-value [3]		0.267		0.003	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
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Table 35.2.11.4.2.5a
Summary of Mastocytosis in Skin by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	5	15	14	33	
Mean (StdDev)	23.0 (40.02)	3.8 (4.83)	20.6 (35.45)	9.2 (20.70)	
Median	1.0	2.0	2.5	1.0	
Min, Max	0, 93	0, 18	0, 98	0, 83	
C7D1 CFB					
n	5	15	14	33	
LS Mean (StdErr) [2]	0.34 (1.329)	-1.89 (0.800)	1.08 (2.117)	-3.35 (1.530)	
95% CI [2]	-2.46, 3.15	-3.58, -0.20	-3.18, 5.35	-6.43, -0.26	
Difference (95% CI) in CFB [2]		-2.23 (-5.30, 0.83)		-4.43 (-9.35, 0.49)	
Hedges'G (95% CI) in CFB		-0.70 (-1.90, 0.33)		-0.51 (-1.19, 0.12)	
p-value [3]		0.143		0.077	
					0.586

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-ism-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.5a
Summary of Mastocytosis in Skin by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	11	21	24	43	
Mean (StdDev)	19.9 (30.68)	4.1 (5.08)	14.6 (25.49)	8.5 (18.64)	
Median	1.0	2.0	3.0	1.0	
Min, Max	0, 91	0, 19	0, 89	0, 91	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-ism-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.5a
Summary of Mastocytosis in Skin by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	6	17	19	30	
Mean (StdDev)	15.0 (29.00)	2.5 (4.16)	19.1 (30.35)	6.8 (14.46)	
Median	1.0	1.0	3.0	1.5	
Min, Max	0, 73	0, 16	0, 85	0, 56	
C4D1 CFB					
n	6	17	19	30	
LS Mean (StdErr) [2]	-2.74 (1.695)	-0.95 (1.140)	1.57 (1.769)	-1.44 (1.577)	
95% CI [2]	-6.27, 0.80	-3.33, 1.43	-1.99, 5.14	-4.62, 1.73	
Difference (95% CI) in CFB [2]		1.79 (-1.97, 5.54)		-3.02 (-7.32, 1.28)	
p-value [3]		0.333		0.164	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-ism-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.5a
Summary of Mastocytosis in Skin by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	5	15	14	33	
Mean (StdDev)	22.4 (40.10)	2.9 (3.75)	15.1 (25.66)	6.2 (15.11)	
Median	1.0	2.0	2.5	1.0	
Min, Max	0, 93	0, 14	0, 79	0, 81	
C7D1 CFB					
n	5	15	14	33	
LS Mean (StdErr) [2]	0.99 (1.031)	-1.56 (0.621)	-1.37 (2.700)	-2.99 (1.952)	
95% CI [2]	-1.18, 3.17	-2.87, -0.25	-6.82, 4.07	-6.92, 0.95	
Difference (95% CI) in CFB [2]		-2.55 (-4.93, -0.18)		-1.61 (-7.89, 4.67)	
Hedges'G (95% CI) in CFB		-1.03 (-2.31, -0.01)		-0.15 (-0.80, 0.49)	
p-value [3]		0.037		0.607	
					0.849

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-ism-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.5a
Summary of Mastocytosis in Skin by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	11	20	24	43	
Mean (StdDev)	16.7 (25.94)	2.9 (3.61)	14.1 (27.50)	8.9 (21.86)	
Median	2.0	1.0	1.5	2.0	
Min, Max	0, 84	0, 12	0, 92	0, 99	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-ism-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.5a
Summary of Mastocytosis in Skin by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	6	16	19	30	
Mean (StdDev)	9.7 (15.55)	1.9 (2.31)	16.1 (32.39)	5.0 (16.20)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 38	0, 9	0, 97	0, 86	
C4D1 CFB					
n	6	16	19	30	
LS Mean (StdErr) [2]	-1.20 (0.840)	-0.87 (0.570)	0.90 (2.268)	-2.83 (2.022)	
95% CI [2]	-2.96, 0.56	-2.07, 0.32	-3.66, 5.47	-6.89, 1.24	
Difference (95% CI) in CFB [2]		0.32 (-1.55, 2.20)		-3.73 (-9.24, 1.78)	
p-value [3]		0.721		0.180	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-ism-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.5a
Summary of Mastocytosis in Skin by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	5	15	14	33	
Mean (StdDev)	10.2 (13.97)	2.2 (2.60)	14.6 (30.31)	6.9 (19.33)	
Median	1.0	1.0	1.5	1.0	
Min, Max	0, 30	0, 10	0, 98	0, 83	
C7D1 CFB					
n	5	15	14	33	
LS Mean (StdErr) [2]	-2.24 (1.582)	-1.27 (0.952)	-0.32 (3.174)	-3.88 (2.294)	
95% CI [2]	-5.58, 1.10	-3.28, 0.73	-6.72, 6.07	-8.50, 0.75	
Difference (95% CI) in CFB [2]		0.96 (-2.68, 4.61)		-3.55 (-10.93, 3.82)	
Hedges'G (95% CI) in CFB		0.25 (-0.80, 1.37)		-0.27 (-0.93, 0.36)	
p-value [3]		0.584		0.337	
					0.448

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-ism-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.5a
Summary of Mastocytosis in Skin by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	11	21	24	43	
Mean (StdDev)	20.0 (29.69)	4.6 (5.40)	18.7 (29.46)	9.6 (19.03)	
Median	2.0	3.0	3.0	3.0	
Min, Max	0, 82	0, 22	0, 88	0, 86	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-ism-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.5a
Summary of Mastocytosis in Skin by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	6	17	19	30	
Mean (StdDev)	14.7 (25.07)	3.1 (4.18)	21.6 (31.77)	7.9 (15.24)	
Median	2.5	2.0	3.0	2.0	
Min, Max	0, 64	0, 17	0, 78	0, 61	
C4D1 CFB					
n	6	17	19	30	
LS Mean (StdErr) [2]	-1.39 (1.121)	-1.42 (0.753)	0.06 (1.241)	-1.19 (1.106)	
95% CI [2]	-3.73, 0.95	-2.99, 0.15	-2.44, 2.55	-3.42, 1.04	
Difference (95% CI) in CFB [2]		-0.03 (-2.51, 2.45)		-1.25 (-4.26, 1.77)	
p-value [3]		0.978		0.409	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-ism-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.5a
Summary of Mastocytosis in Skin by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	5	15	14	33	
Mean (StdDev)	19.6 (32.62)	3.9 (4.85)	16.7 (29.94)	8.1 (17.53)	
Median	1.0	2.0	2.5	1.0	
Min, Max	0, 76	0, 18	0, 91	0, 87	
C7D1 CFB					
n	5	15	14	33	
LS Mean (StdErr) [2]	0.81 (1.092)	-1.46 (0.658)	-1.81 (3.295)	-2.23 (2.382)	
95% CI [2]	-1.50, 3.11	-2.85, -0.07	-8.45, 4.83	-7.03, 2.57	
Difference (95% CI) in CFB [2]		-2.27 (-4.79, 0.25)		-0.42 (-8.08, 7.24)	
Hedges'G (95% CI) in CFB		-0.86 (-2.10, 0.16)		-0.03 (-0.68, 0.61)	
p-value [3]		0.075		0.913	
					0.756

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-ism-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.5a
Summary of Mastocytosis in Skin by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	11	21	24	43	
Mean (StdDev)	14.5 (22.79)	2.5 (3.14)	10.8 (21.62)	7.6 (17.54)	
Median	1.0	1.0	1.0	2.0	
Min, Max	0, 76	0, 11	0, 84	0, 84	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-ism-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.5a
Summary of Mastocytosis in Skin by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	6	17	19	30	
Mean (StdDev)	9.2 (13.29)	1.7 (2.37)	14.4 (28.33)	4.3 (11.33)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 30	0, 9	0, 90	0, 58	
C4D1 CFB					
n	6	17	19	30	
LS Mean (StdErr) [2]	0.37 (0.653)	-0.86 (0.439)	2.15 (1.511)	-2.54 (1.346)	
95% CI [2]	-0.99, 1.73	-1.78, 0.05	-0.89, 5.19	-5.25, 0.17	
Difference (95% CI) in CFB [2]		-1.23 (-2.68, 0.21)		-4.69 (-8.36, -1.02)	
p-value [3]		0.091		0.013	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-ism-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.5a
Summary of Mastocytosis in Skin by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	5	15	14	33	
Mean (StdDev)	11.4 (15.95)	1.7 (2.22)	11.5 (22.90)	5.3 (14.55)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 35	0, 7	0, 65	0, 65	
C7D1 CFB					
n	5	15	14	33	
LS Mean (StdErr) [2]	1.07 (1.223)	-1.41 (0.737)	0.95 (1.840)	-4.37 (1.330)	
95% CI [2]	-1.51, 3.65	-2.97, 0.14	-2.76, 4.66	-7.05, -1.69	
Difference (95% CI) in CFB [2]		-2.48 (-5.30, 0.34)		-5.32 (-9.60, -1.04)	
Hedges'G (95% CI) in CFB		-0.84 (-2.08, 0.18)		-0.70 (-1.40, -0.08)	
p-value [3]		0.081		0.016	
					0.413

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-ism-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.6a
Summary of Mastocytosis in Skin by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	6	14	29	50	
Mean (StdDev)	3.0 (3.29)	9.3 (23.66)	24.1 (32.97)	8.7 (16.95)	
Median	2.0	2.0	3.0	2.5	
Min, Max	0, 7	0, 91	0, 92	0, 81	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-tryp-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.6a
Summary of Mastocytosis in Skin by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	6	8	19	39	
Mean (StdDev)	3.3 (3.39)	2.5 (2.56)	27.9 (37.04)	7.7 (17.86)	
Median	2.0	1.5	3.0	2.0	
Min, Max	0, 8	0, 8	0, 97	0, 86	
C4D1 CFB					
n	6	8	19	39	
LS Mean (StdErr) [2]	0.23 (0.366)	-0.54 (0.290)	0.02 (1.039)	-2.16 (0.717)	
95% CI [2]	-0.57, 1.04	-1.18, 0.10	-2.06, 2.11	-3.60, -0.72	
Difference (95% CI) in CFB [2]		-0.77 (-1.75, 0.21)		-2.18 (-4.63, 0.27)	
p-value [3]		0.112		0.079	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-tryp-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.6a
Summary of Mastocytosis in Skin by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	5	11	14	37	
Mean (StdDev)	3.2 (3.49)	9.0 (24.00)	27.6 (39.73)	7.1 (15.42)	
Median	1.0	1.0	2.5	1.0	
Min, Max	0, 7	0, 81	0, 98	0, 83	
C7D1 CFB					
n	5	11	14	37	
LS Mean (StdErr) [2]	0.43 (1.186)	-2.08 (0.773)	1.18 (2.034)	-3.08 (1.299)	
95% CI [2]	-2.13, 2.99	-3.75, -0.41	-2.91, 5.27	-5.69, -0.46	
Difference (95% CI) in CFB [2]		-2.51 (-5.45, 0.43)		-4.25 (-8.92, 0.41)	
Hedges'G (95% CI) in CFB		-0.91 (-2.29, 0.15)		-0.53 (-1.20, 0.08)	
p-value [3]		0.089		0.073	
					0.675

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-tryp-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.6a
Summary of Mastocytosis in Skin by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	6	14	29	50	
Mean (StdDev)	2.7 (2.58)	8.8 (23.78)	19.1 (28.78)	6.6 (12.76)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 7	0, 91	0, 91	0, 75	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-tryp-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.6a
Summary of Mastocytosis in Skin by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	6	8	19	39	
Mean (StdDev)	2.7 (2.16)	1.8 (1.98)	22.9 (32.45)	6.0 (12.97)	
Median	2.5	2.0	2.0	1.0	
Min, Max	0, 6	0, 6	0, 85	0, 56	
C4D1 CFB					
n	6	8	19	39	
LS Mean (StdErr) [2]	0.08 (0.406)	-0.85 (0.322)	0.23 (1.692)	-1.64 (1.168)	
95% CI [2]	-0.82, 0.97	-1.56, -0.14	-3.16, 3.62	-3.98, 0.70	
Difference (95% CI) in CFB [2]		-0.92 (-2.01, 0.16)		-1.87 (-5.86, 2.12)	
p-value [3]		0.089		0.351	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-tryp-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.6a
Summary of Mastocytosis in Skin by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	5	11	14	37	
Mean (StdDev)	2.6 (2.41)	8.8 (24.01)	22.1 (32.54)	4.1 (6.79)	
Median	2.0	2.0	2.5	1.0	
Min, Max	0, 6	0, 81	0, 93	0, 27	
C7D1 CFB					
n	5	11	14	37	
LS Mean (StdErr) [2]	0.34 (1.242)	-1.30 (0.810)	-1.18 (2.564)	-3.13 (1.638)	
95% CI [2]	-2.34, 3.03	-3.05, 0.45	-6.34, 3.97	-6.42, 0.16	
Difference (95% CI) in CFB [2]		-1.64 (-4.72, 1.44)		-1.95 (-7.83, 3.93)	
Hedges'G (95% CI) in CFB		-0.57 (-1.85, 0.51)		-0.19 (-0.84, 0.43)	
p-value [3]		0.270		0.508	
					0.972

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-tryp-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.6a
Summary of Mastocytosis in Skin by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	6	14	29	49	
Mean (StdDev)	1.0 (0.89)	9.0 (25.98)	17.8 (28.51)	6.4 (15.79)	
Median	1.0	1.5	2.0	1.0	
Min, Max	0, 2	0, 99	0, 92	0, 81	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-tryp-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.6a
Summary of Mastocytosis in Skin by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	6	8	19	38	
Mean (StdDev)	0.8 (0.98)	1.1 (0.99)	18.8 (32.31)	4.5 (14.44)	
Median	0.5	1.0	1.0	1.0	
Min, Max	0, 2	0, 3	0, 97	0, 86	
C4D1 CFB					
n	6	8	19	38	
LS Mean (StdErr) [2]	-0.19 (0.428)	-0.88 (0.339)	0.56 (2.072)	-2.55 (1.459)	
95% CI [2]	-1.13, 0.75	-1.63, -0.14	-3.59, 4.72	-5.47, 0.38	
Difference (95% CI) in CFB [2]		-0.69 (-1.84, 0.45)		-3.11 (-8.00, 1.79)	
p-value [3]		0.211		0.209	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-tryp-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.6a
Summary of Mastocytosis in Skin by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	5	11	14	37	
Mean (StdDev)	0.6 (0.89)	7.6 (21.70)	18.0 (29.96)	4.8 (14.44)	
Median	0.0	1.0	2.5	1.0	
Min, Max	0, 2	0, 73	0, 98	0, 83	
C7D1 CFB					
n	5	11	14	37	
LS Mean (StdErr) [2]	0.52 (3.122)	-3.13 (2.035)	-0.78 (2.930)	-2.64 (1.872)	
95% CI [2]	-6.22, 7.26	-7.52, 1.27	-6.67, 5.11	-6.41, 1.12	
Difference (95% CI) in CFB [2]		-3.65 (-11.39, 4.09)		-1.86 (-8.58, 4.85)	
Hedges'G (95% CI) in CFB		-0.51 (-1.77, 0.58)		-0.16 (-0.80, 0.46)	
p-value [3]		0.327		0.580	
					0.800

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-tryp-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.6a
Summary of Mastocytosis in Skin by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	6	14	29	50	
Mean (StdDev)	3.2 (3.13)	9.1 (22.30)	22.4 (30.99)	7.7 (14.04)	
Median	2.0	3.0	3.0	2.5	
Min, Max	0, 7	0, 86	0, 88	0, 81	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-tryp-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.6a
Summary of Mastocytosis in Skin by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	6	8	19	39	
Mean (StdDev)	3.5 (3.27)	2.8 (2.49)	25.1 (32.78)	6.9 (13.68)	
Median	2.5	2.5	3.0	2.0	
Min, Max	0, 8	0, 8	0, 78	0, 61	
C4D1 CFB					
n	6	8	19	39	
LS Mean (StdErr) [2]	-0.00 (0.637)	-1.00 (0.506)	-0.83 (1.158)	-1.72 (0.800)	
95% CI [2]	-1.40, 1.40	-2.11, 0.11	-3.15, 1.49	-3.32, -0.12	
Difference (95% CI) in CFB [2]		-1.00 (-2.71, 0.71)		-0.88 (-3.62, 1.85)	
p-value [3]		0.224		0.519	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-tryp-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.6a
Summary of Mastocytosis in Skin by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	5	11	14	37	
Mean (StdDev)	3.2 (3.49)	9.5 (25.83)	22.6 (33.41)	6.0 (9.97)	
Median	1.0	1.0	2.5	1.0	
Min, Max	0, 7	0, 87	0, 91	0, 40	
C7D1 CFB					
n	5	11	14	37	
LS Mean (StdErr) [2]	-0.06 (0.434)	-1.12 (0.283)	-1.56 (3.153)	-2.45 (2.014)	
95% CI [2]	-0.99, 0.88	-1.73, -0.51	-7.90, 4.78	-6.50, 1.60	
Difference (95% CI) in CFB [2]		-1.06 (-2.14, 0.02)		-0.89 (-8.12, 6.34)	
Hedges'G (95% CI) in CFB		-1.06 (-2.48, -0.00)		-0.07 (-0.71, 0.56)	
p-value [3]		0.053		0.806	
					0.932

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-tryp-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.6a
Summary of Mastocytosis in Skin by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	6	14	29	50	
Mean (StdDev)	0.7 (0.82)	8.1 (22.01)	14.2 (23.25)	5.3 (12.04)	
Median	0.5	1.0	2.0	2.0	
Min, Max	0, 2	0, 84	0, 84	0, 76	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.11.4.2.6a
Summary of Mastocytosis in Skin by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	6	8	19	39	
Mean (StdDev)	0.7 (0.52)	2.0 (1.85)	17.1 (28.11)	3.7 (10.06)	
Median	1.0	1.5	2.0	1.0	
Min, Max	0, 1	0, 5	0, 90	0, 58	
C4D1 CFB					
n	6	8	19	39	
LS Mean (StdErr) [2]	0.02 (0.643)	-0.37 (0.510)	2.32 (1.355)	-2.27 (0.936)	
95% CI [2]	-1.40, 1.43	-1.49, 0.75	-0.40, 5.03	-4.15, -0.40	
Difference (95% CI) in CFB [2]		-0.38 (-2.11, 1.34)		-4.59 (-7.78, -1.39)	
p-value [3]		0.633		0.006	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-tryp-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.6a
Summary of Mastocytosis in Skin by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	5	11	14	37	
Mean (StdDev)	0.6 (0.55)	6.0 (15.67)	15.4 (23.25)	3.6 (11.14)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 1	0, 53	0, 65	0, 65	
C7D1 CFB					
n	5	11	14	37	
LS Mean (StdErr) [2]	1.26 (3.688)	-3.52 (2.405)	1.92 (1.428)	-2.54 (0.912)	
95% CI [2]	-6.71, 9.23	-8.71, 1.68	-0.95, 4.79	-4.37, -0.70	
Difference (95% CI) in CFB [2]		-4.78 (-13.92, 4.37)		-4.46 (-7.73, -1.18)	
Hedges'G (95% CI) in CFB		-0.56 (-1.84, 0.52)		-0.80 (-1.49, -0.18)	
p-value [3]		0.279		0.009	
					>0.999

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-tryp-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.7a
Summary of Mastocytosis in Skin by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	34	60	1	4	
Mean (StdDev)	21.0 (31.33)	7.9 (16.46)	3.0 (-)	23.3 (38.66)	
Median	2.5	2.0	3.0	5.5	
Min, Max	0, 92	0, 91	3, 3	1, 81	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-ecog-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.7a
Summary of Mastocytosis in Skin by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	24	44	1	3	
Mean (StdDev)	22.8 (34.35)	5.3 (11.73)	3.0 (-)	30.3 (48.27)	
Median	3.0	2.0	3.0	5.0	
Min, Max	0, 97	0, 61	3, 3	0, 86	
C4D1 CFB					
n	24	44	1	3	
LS Mean (StdErr) [2]	0.29 (0.905)	-1.69 (0.726)	-1.25 (7.462)	-0.75 (3.897)	
95% CI [2]	-1.52, 2.09	-3.14, -0.24	-96.07, 93.57	-50.27, 48.77	
Difference (95% CI) in CFB [2]		-1.98 (-4.01, 0.05)		0.50 (-98.54, 99.54)	
p-value [3]		0.056		0.959	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-ecog-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.7a
Summary of Mastocytosis in Skin by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	18	45	1	3	
Mean (StdDev)	22.2 (36.31)	6.1 (13.89)	3.0 (-)	29.0 (46.81)	
Median	1.5	1.0	3.0	4.0	
Min, Max	0, 98	0, 81	3, 3	0, 83	
C7D1 CFB					
n	18	45	1	3	
LS Mean (StdErr) [2]	1.19 (1.694)	-2.79 (1.161)	0.00 (3.512)	-1.33 (2.028)	
95% CI [2]	-2.20, 4.58	-5.12, -0.47	-15.11, 15.11	-10.06, 7.39	
Difference (95% CI) in CFB [2]		-3.98 (-7.74, -0.22)		-1.33 (-18.78, 16.11)	
Hedges'G (95% CI) in CFB		-0.52 (-1.10, 0.03)		NE	
p-value [3]		0.039		0.774	
					0.739

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-ecog-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.7a
Summary of Mastocytosis in Skin by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	34	60	1	4	
Mean (StdDev)	16.7 (27.15)	7.1 (16.05)	1.0 (-)	7.0 (7.70)	
Median	3.0	2.0	1.0	5.5	
Min, Max	0, 91	0, 91	1, 1	0, 17	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-ecog-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.7a
Summary of Mastocytosis in Skin by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	24	44	1	3	
Mean (StdDev)	18.8 (29.92)	4.5 (10.60)	2.0 (-)	17.0 (25.24)	
Median	2.5	1.0	2.0	5.0	
Min, Max	0, 85	0, 56	2, 2	0, 46	
C4D1 CFB					
n	24	44	1	3	
LS Mean (StdErr) [2]	0.36 (1.234)	-1.90 (0.990)	-6.25 (27.362)	5.25 (14.289)	
95% CI [2]	-2.10, 2.83	-3.88, 0.08	-353.92, 341.42	-176.31, 186.81	
Difference (95% CI) in CFB [2]		-2.26 (-5.04, 0.51)		11.50 (-351.63, 374.63)	
p-value [3]		0.108		0.756	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-ecog-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.7a
Summary of Mastocytosis in Skin by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	18	45	1	3	
Mean (StdDev)	17.8 (29.69)	4.9 (12.82)	3.0 (-)	9.3 (12.86)	
Median	2.0	1.0	3.0	4.0	
Min, Max	0, 93	0, 81	3, 3	0, 24	
C7D1 CFB					
n	18	45	1	3	
LS Mean (StdErr) [2]	-0.35 (2.095)	-2.35 (1.436)	2.00 (6.028)	0.67 (3.480)	
95% CI [2]	-4.54, 3.84	-5.22, 0.53	-23.94, 27.94	-14.31, 15.64	
Difference (95% CI) in CFB [2]		-2.00 (-6.65, 2.66)		-1.33 (-31.28, 28.61)	
Hedges'G (95% CI) in CFB		-0.21 (-0.78, 0.34)		NE	
p-value [3]		0.394		0.866	
					0.946

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-ecog-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.7a
Summary of Mastocytosis in Skin by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	34	59	1	4	
Mean (StdDev)	15.3 (26.98)	6.0 (16.18)	3.0 (-)	21.5 (39.68)	
Median	1.5	1.0	3.0	2.0	
Min, Max	0, 92	0, 99	3, 3	1, 81	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-ecog-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.7a
Summary of Mastocytosis in Skin by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	24	43	1	3	
Mean (StdDev)	15.0 (29.59)	2.2 (4.65)	3.0 (-)	29.0 (49.37)	
Median	1.0	1.0	3.0	1.0	
Min, Max	0, 97	0, 28	3, 3	0, 86	
C4D1 CFB					
n	24	43	1	3	
LS Mean (StdErr) [2]	0.74 (1.819)	-2.11 (1.471)	-1.25 (5.804)	0.25 (3.031)	
95% CI [2]	-2.89, 4.38	-5.05, 0.83	-75.00, 72.50	-38.26, 38.76	
Difference (95% CI) in CFB [2]		-2.85 (-6.94, 1.25)		1.50 (-75.53, 78.53)	
p-value [3]		0.169		0.846	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
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Table 35.2.11.4.2.7a
Summary of Mastocytosis in Skin by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	18	45	1	3	
Mean (StdDev)	14.0 (27.31)	3.9 (11.79)	3.0 (-)	28.0 (47.63)	
Median	1.0	1.0	3.0	1.0	
Min, Max	0, 98	0, 73	3, 3	0, 83	
C7D1 CFB					
n	18	45	1	3	
LS Mean (StdErr) [2]	-0.51 (2.533)	-2.91 (1.736)	0.00 (2.082)	-0.33 (1.202)	
95% CI [2]	-5.58, 4.56	-6.39, 0.56	-8.96, 8.96	-5.50, 4.84	
Difference (95% CI) in CFB [2]		-2.41 (-8.03, 3.22)		-0.33 (-10.68, 10.01)	
Hedges'G (95% CI) in CFB		-0.21 (-0.78, 0.34)		NE	
p-value [3]		0.395		0.902	
					0.861

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-ecog-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.7a
Summary of Mastocytosis in Skin by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	34	60	1	4	
Mean (StdDev)	19.6 (29.40)	7.7 (16.03)	3.0 (-)	12.5 (17.37)	
Median	2.5	3.0	3.0	5.5	
Min, Max	0, 88	0, 86	3, 3	1, 38	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
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Table 35.2.11.4.2.7a
Summary of Mastocytosis in Skin by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	24	44	1	3	
Mean (StdDev)	20.6 (30.38)	5.5 (11.66)	3.0 (-)	16.0 (23.52)	
Median	3.0	2.0	3.0	5.0	
Min, Max	0, 78	0, 61	3, 3	0, 43	
C4D1 CFB					
n	24	44	1	3	
LS Mean (StdErr) [2]	-0.34 (1.013)	-1.34 (0.813)	-1.25 (7.462)	-0.75 (3.897)	
95% CI [2]	-2.36, 1.68	-2.96, 0.28	-96.07, 93.57	-50.27, 48.77	
Difference (95% CI) in CFB [2]		-1.00 (-3.28, 1.28)		0.50 (-98.54, 99.54)	
p-value [3]		0.383		0.959	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-ecog-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.7a
Summary of Mastocytosis in Skin by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	18	45	1	3	
Mean (StdDev)	18.3 (30.41)	6.4 (14.73)	3.0 (-)	12.3 (18.82)	
Median	1.5	1.0	3.0	3.0	
Min, Max	0, 91	0, 87	3, 3	0, 34	
C7D1 CFB					
n	18	45	1	3	
LS Mean (StdErr) [2]	-0.77 (2.603)	-1.64 (1.785)	0.00 (2.517)	-3.67 (1.453)	
95% CI [2]	-5.98, 4.44	-5.21, 1.93	-10.83, 10.83	-9.92, 2.58	
Difference (95% CI) in CFB [2]		-0.87 (-6.65, 4.91)		-3.67 (-16.17, 8.84)	
Hedges'G (95% CI) in CFB		-0.07 (-0.63, 0.48)		NE	
p-value [3]		0.765		0.334	
					0.818

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-ecog-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.7a
Summary of Mastocytosis in Skin by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	34	60	1	4	
Mean (StdDev)	12.2 (21.97)	4.9 (11.98)	1.0 (-)	20.8 (36.88)	
Median	1.0	1.5	1.0	3.0	
Min, Max	0, 84	0, 84	1, 1	1, 76	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-ecog-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.7a
Summary of Mastocytosis in Skin by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	24	44	1	3	
Mean (StdDev)	13.7 (25.79)	2.3 (4.40)	1.0 (-)	20.0 (32.92)	
Median	1.0	1.0	1.0	2.0	
Min, Max	0, 90	0, 27	1, 1	0, 58	
C4D1 CFB					
n	24	44	1	3	
LS Mean (StdErr) [2]	1.73 (1.130)	-1.65 (0.906)	4.75 (12.437)	-5.75 (6.495)	
95% CI [2]	-0.52, 3.99	-3.46, 0.16	-153.28, 162.78	-88.28, 76.78	
Difference (95% CI) in CFB [2]		-3.39 (-5.93, -0.85)		-10.50 (-175.56, 154.56)	
p-value [3]		0.010		0.567	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-ecog-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.7a
Summary of Mastocytosis in Skin by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	18	45	1	3	
Mean (StdDev)	12.1 (21.31)	3.0 (8.50)	1.0 (-)	21.7 (37.53)	
Median	1.0	1.0	1.0	0.0	
Min, Max	0, 65	0, 53	1, 1	0, 65	
C7D1 CFB					
n	18	45	1	3	
LS Mean (StdErr) [2]	1.35 (1.471)	-3.01 (1.008)	0.00 (5.033)	-5.67 (2.906)	
95% CI [2]	-1.60, 4.29	-5.03, -1.00	-21.66, 21.66	-18.17, 6.84	
Difference (95% CI) in CFB [2]		-4.36 (-7.63, -1.09)		-5.67 (-30.67, 19.34)	
Hedges'G (95% CI) in CFB		-0.65 (-1.24, -0.10)		NE	
p-value [3]		0.010		0.432	
					0.851

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-ecog-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.8a
Summary of Mastocytosis in Skin by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	5	32	59	
Mean (StdDev)	39.7 (45.79)	21.2 (39.19)	18.7 (29.68)	7.8 (15.75)	
Median	20.0	3.0	2.0	2.0	
Min, Max	7, 92	1, 91	0, 91	0, 81	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-thpy-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.8a
Summary of Mastocytosis in Skin by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	3	2	22	45	
Mean (StdDev)	40.7 (49.10)	3.0 (1.41)	19.5 (32.00)	7.0 (16.73)	
Median	18.0	3.0	2.5	2.0	
Min, Max	7, 97	2, 4	0, 85	0, 86	
C4D1 CFB					
n	3	2	22	45	
LS Mean (StdErr) [2]	-1.00 (3.500)	-8.50 (7.000)	0.19 (0.962)	-1.52 (0.730)	
95% CI [2]	-45.47, 43.47	-97.44, 80.44	-1.73, 2.12	-2.98, -0.06	
Difference (95% CI) in CFB [2]		-7.50 (-84.53, 69.53)		-1.72 (-3.82, 0.39)	
p-value [3]		0.433		0.109	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-thpy-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.8a
Summary of Mastocytosis in Skin by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	4	16	44	
Mean (StdDev)	41.7 (49.22)	21.0 (40.01)	17.4 (33.10)	6.3 (14.27)	
Median	20.0	1.5	1.0	1.0	
Min, Max	7, 98	0, 81	0, 93	0, 83	
C7D1 CFB					
n	3	4	16	44	
LS Mean (StdErr) [2]	-0.15 (2.329)	-9.55 (3.245)	1.06 (1.830)	-2.39 (1.201)	
95% CI [2]	-7.56, 7.26	-19.88, 0.78	-2.60, 4.73	-4.79, 0.02	
Difference (95% CI) in CFB [2]		-9.40 (-19.57, 0.77)		-3.45 (-7.44, 0.53)	
Hedges'G (95% CI) in CFB		-1.40 (-4.55, 0.10)		-0.44 (-1.04, 0.14)	
p-value [3]		0.060		0.088	
					0.583

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-thpy-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.8a
Summary of Mastocytosis in Skin by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	5	32	59	
Mean (StdDev)	37.3 (44.97)	20.0 (39.77)	14.3 (24.80)	6.0 (11.85)	
Median	16.0	3.0	1.0	2.0	
Min, Max	7, 89	0, 91	0, 91	0, 75	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-thpy-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.8a
Summary of Mastocytosis in Skin by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	3	2	22	45	
Mean (StdDev)	33.3 (39.80)	1.0 (0.00)	16.0 (28.36)	5.5 (12.16)	
Median	15.0	1.0	2.0	2.0	
Min, Max	6, 79	1, 1	0, 85	0, 56	
C4D1 CFB					
n	3	2	22	45	
LS Mean (StdErr) [2]	-1.00 (3.000)	7.00 (6.000)	0.57 (1.554)	-1.55 (1.179)	
95% CI [2]	-39.12, 37.12	-69.24, 83.24	-2.53, 3.68	-3.90, 0.81	
Difference (95% CI) in CFB [2]		8.00 (-58.02, 74.02)		-2.12 (-5.52, 1.28)	
p-value [3]		0.367		0.218	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
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Table 35.2.11.4.2.8a
Summary of Mastocytosis in Skin by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	4	16	44	
Mean (StdDev)	27.3 (27.97)	20.8 (40.17)	15.1 (29.72)	3.8 (6.31)	
Median	17.0	1.0	1.5	2.0	
Min, Max	6, 59	0, 81	0, 93	0, 27	
C7D1 CFB					
n	3	4	16	44	
LS Mean (StdErr) [2]	-5.65 (7.951)	7.95 (11.078)	1.30 (2.077)	-2.26 (1.363)	
95% CI [2]	-30.96, 19.66	-27.31, 43.21	-2.87, 5.46	-4.99, 0.47	
Difference (95% CI) in CFB [2]		13.60 (-21.12, 48.32)		-3.55 (-8.08, 0.97)	
Hedges'G (95% CI) in CFB		0.59 (-1.08, 2.98)		-0.40 (-1.00, 0.18)	
p-value [3]		0.301		0.122	
					0.104

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-thpy-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.8a
Summary of Mastocytosis in Skin by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	5	32	58	
Mean (StdDev)	38.0 (47.62)	21.4 (43.39)	12.8 (24.02)	5.7 (14.60)	
Median	20.0	2.0	1.0	1.0	
Min, Max	2, 92	1, 99	0, 86	0, 81	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-thpy-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.8a
Summary of Mastocytosis in Skin by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	3	2	22	44	
Mean (StdDev)	39.0 (50.86)	1.0 (0.00)	11.2 (24.94)	4.1 (13.45)	
Median	18.0	1.0	1.0	1.0	
Min, Max	2, 97	1, 1	0, 93	0, 86	
C4D1 CFB					
n	3	2	22	44	
LS Mean (StdErr) [2]	-1.00 (0.500)	-7.50 (1.000)	0.70 (1.943)	-1.93 (1.484)	
95% CI [2]	-7.35, 5.35	-20.21, 5.21	-3.18, 4.58	-4.90, 1.03	
Difference (95% CI) in CFB [2]		-6.50 (-17.50, 4.50)		-2.63 (-6.89, 1.62)	
p-value [3]		0.084		0.221	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-thpy-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.8a
Summary of Mastocytosis in Skin by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	4	16	44	
Mean (StdDev)	40.0 (51.03)	19.3 (35.84)	8.4 (18.38)	4.2 (13.29)	
Median	20.0	1.5	1.0	1.0	
Min, Max	2, 98	1, 73	0, 70	0, 83	
C7D1 CFB					
n	3	4	16	44	
LS Mean (StdErr) [2]	-2.90 (4.033)	-17.30 (5.619)	-0.66 (2.644)	-2.01 (1.734)	
95% CI [2]	-15.73, 9.93	-35.18, 0.58	-5.96, 4.63	-5.49, 1.46	
Difference (95% CI) in CFB [2]		-14.40 (-32.01, 3.21)		-1.35 (-7.11, 4.41)	
Hedges'G (95% CI) in CFB		-1.24 (-4.22, 0.28)		-0.12 (-0.71, 0.46)	
p-value [3]		0.080		0.641	
					0.365

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-thpy-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.8a
Summary of Mastocytosis in Skin by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	5	32	59	
Mean (StdDev)	37.7 (43.94)	19.8 (37.21)	17.3 (27.70)	7.0 (13.04)	
Median	18.0	1.0	2.0	3.0	
Min, Max	7, 88	1, 86	0, 82	0, 81	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-thpy-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.8a
Summary of Mastocytosis in Skin by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	3	2	22	45	
Mean (StdDev)	30.0 (30.81)	3.0 (1.41)	18.5 (30.30)	6.3 (12.83)	
Median	18.0	3.0	2.5	2.0	
Min, Max	7, 65	2, 4	0, 78	0, 61	
C4D1 CFB					
n	3	2	22	45	
LS Mean (StdErr) [2]	-0.00 (3.500)	20.50 (7.000)	0.36 (0.837)	-1.46 (0.635)	
95% CI [2]	-44.47, 44.47	-68.44, 109.44	-1.31, 2.03	-2.73, -0.19	
Difference (95% CI) in CFB [2]		20.50 (-56.53, 97.53)		-1.82 (-3.66, 0.01)	
p-value [3]		0.183		0.051	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-thpy-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.8a
Summary of Mastocytosis in Skin by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	4	16	44	
Mean (StdDev)	18.3 (10.60)	22.5 (43.01)	17.3 (32.37)	5.3 (9.31)	
Median	20.0	1.5	1.0	1.0	
Min, Max	7, 28	0, 87	0, 91	0, 40	
C7D1 CFB					
n	3	4	16	44	
LS Mean (StdErr) [2]	-7.40 (11.776)	27.20 (16.406)	2.11 (1.893)	-2.32 (1.242)	
95% CI [2]	-44.88, 30.08	-25.01, 79.41	-1.68, 5.90	-4.81, 0.16	
Difference (95% CI) in CFB [2]		34.60 (-16.82, 86.02)		-4.44 (-8.56, -0.31)	
Hedges'G (95% CI) in CFB		1.02 (-0.54, 3.79)		-0.54 (-1.16, 0.03)	
p-value [3]		0.122		0.036	
					0.004

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-thpy-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.8a
Summary of Mastocytosis in Skin by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	5	32	59	
Mean (StdDev)	27.0 (28.21)	18.0 (36.95)	10.5 (21.03)	4.9 (11.17)	
Median	23.0	1.0	1.0	2.0	
Min, Max	1, 57	0, 84	0, 84	0, 76	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-thpy-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.8a
Summary of Mastocytosis in Skin by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	3	2	22	45	
Mean (StdDev)	35.3 (42.59)	1.0 (0.00)	10.1 (21.98)	3.5 (9.38)	
Median	22.0	1.0	1.0	1.0	
Min, Max	1, 83	1, 1	0, 90	0, 58	
C4D1 CFB					
n	3	2	22	45	
LS Mean (StdErr) [2]	-0.50 (2.500)	-28.00 (5.000)	1.30 (1.044)	-1.61 (0.791)	
95% CI [2]	-32.27, 31.27	-91.53, 35.53	-0.79, 3.38	-3.19, -0.02	
Difference (95% CI) in CFB [2]		-27.50 (-82.52, 27.52)		-2.90 (-5.19, -0.62)	
p-value [3]		0.099		0.014	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-thpy-a.sas Date: 16:01/07AUG2023

Table 35.2.11.4.2.8a
Summary of Mastocytosis in Skin by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	4	16	44	
Mean (StdDev)	29.0 (32.74)	13.8 (26.17)	8.2 (17.50)	3.3 (10.25)	
Median	21.0	1.0	1.0	1.0	
Min, Max	1, 65	0, 53	0, 64	0, 65	
C7D1 CFB					
n	3	4	16	44	
LS Mean (StdErr) [2]	-4.30 (4.749)	-22.10 (6.617)	1.71 (1.267)	-2.11 (0.831)	
95% CI [2]	-19.41, 10.81	-43.16, -1.04	-0.83, 4.25	-3.77, -0.44	
Difference (95% CI) in CFB [2]		-17.80 (-38.54, 2.94)		-3.82 (-6.58, -1.06)	
Hedges'G (95% CI) in CFB		-1.30 (-4.34, 0.21)		-0.70 (-1.32, -0.13)	
p-value [3]		0.072		0.008	
					0.177

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-pp-thpy-a.sas Date: 16:01/07AUG2023

Table 35.2.8.2.1a
Change from Baseline in MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	54	113	11	6	
Mean (StdDev)	59.34 (16.956)	59.29 (15.650)	52.95 (16.875)	58.64 (12.321)	
Median	61.57	58.33	54.63	62.96	
Min, Max	22.2, 97.2	26.9, 98.1	27.8, 83.3	42.6, 70.4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-age-a.sas Date: 15:52/07AUG2023

Table 35.2.8.2.1a
Change from Baseline in MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	54	113	11	6	
Mean (StdDev)	51.15 (17.060)	46.27 (18.415)	45.29 (15.480)	43.98 (10.122)	
Median	52.78	44.44	40.74	43.52	
Min, Max	19.4, 92.6	14.8, 90.7	16.7, 76.9	32.4, 58.3	
C2D1 CFB					
n	52	110	11	6	
LS Mean (StdErr) [2]	-6.81 (1.923)	-11.98 (1.421)	-11.48 (3.390)	-21.33 (4.943)	
95% CI [2]	-10.60, -3.01	-14.78, -9.17	-18.80, -4.15	-32.01, -10.65	
Difference (95% CI) in CFB [2]		-5.17 (-9.29, -1.05)		-9.85 (-18.16, -1.54)	
p-value [3]		0.014		0.024	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-age-a.sas Date: 15:52/07AUG2023

Table 35.2.8.2.1a
Change from Baseline in MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	53	103	10	6	
Mean (StdDev)	50.58 (19.603)	42.79 (19.028)	44.07 (17.785)	29.48 (7.577)	
Median	50.00	38.89	41.20	28.24	
Min, Max	10.2, 88.0	1.9, 93.5	17.6, 81.5	18.5, 39.8	
C3D1 CFB					
n	51	103	10	6	
LS Mean (StdErr) [2]	-8.28 (2.254)	-15.27 (1.649)	-10.70 (5.229)	-34.09 (7.560)	
95% CI [2]	-12.74, -3.83	-18.53, -12.01	-22.09, 0.70	-50.57, -17.62	
Difference (95% CI) in CFB [2]		-6.99 (-11.81, -2.16)		-23.40 (-36.25, -10.54)	
p-value [3]		0.005		0.002	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-age-a.sas Date: 15:52/07AUG2023

Table 35.2.8.2.1a
Change from Baseline in MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	49	107	7	6	
Mean (StdDev)	50.04 (18.867)	43.25 (20.311)	50.79 (19.536)	29.78 (15.376)	
Median	48.15	40.74	44.44	29.17	
Min, Max	14.8, 80.6	2.8, 90.7	29.6, 87.0	9.3, 49.1	
C4D1 CFB					
n	47	105	7	6	
LS Mean (StdErr) [2]	-9.45 (2.464)	-16.11 (1.781)	-6.05 (6.395)	-31.60 (10.488)	
95% CI [2]	-14.32, -4.58	-19.63, -12.59	-20.52, 8.42	-55.33, -7.88	
Difference (95% CI) in CFB [2]		-6.66 (-11.82, -1.51)		-25.56 (-46.16, -4.95)	
p-value [3]		0.012		0.021	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-age-a.sas Date: 15:52/07AUG2023

Table 35.2.8.2.1a
Change from Baseline in MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	51	103	9	5	
Mean (StdDev)	48.30 (20.612)	41.67 (20.405)	52.26 (17.391)	21.85 (9.812)	
Median	48.15	37.04	51.85	25.00	
Min, Max	10.2, 88.0	4.6, 93.5	29.6, 78.7	5.6, 29.6	
C5D1 CFB					
n	50	99	9	5	
LS Mean (StdErr) [2]	-10.11 (2.510)	-18.06 (1.867)	-6.76 (8.996)	-40.78 (13.815)	
95% CI [2]	-15.07, -5.15	-21.75, -14.37	-26.81, 13.28	-71.56, -10.00	
Difference (95% CI) in CFB [2]		-7.95 (-13.32, -2.58)		-34.02 (-59.25, -8.78)	
p-value [3]		0.004		0.013	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-age-a.sas Date: 15:52/07AUG2023

Table 35.2.8.2.1a
Change from Baseline in MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	50	105	8	6	
Mean (StdDev)	50.80 (20.326)	40.56 (22.202)	48.96 (14.322)	22.69 (8.172)	
Median	50.00	38.89	45.83	20.83	
Min, Max	12.0, 89.8	2.8, 92.6	32.4, 75.9	11.1, 34.3	
C6D1 CFB					
n	49	101	8	6	
LS Mean (StdErr) [2]	-7.43 (2.736)	-18.57 (2.005)	-9.81 (4.694)	-40.94 (7.793)	
95% CI [2]	-12.84, -2.02	-22.53, -14.60	-20.27, 0.65	-58.31, -23.58	
Difference (95% CI) in CFB [2]		-11.14 (-16.99, -5.29)		-31.13 (-46.10, -16.16)	
p-value [3]		<0.001		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.1a
Change from Baseline in MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	48	105	10	6	
Mean (StdDev)	48.38 (21.574)	39.98 (22.568)	47.50 (17.151)	22.38 (7.734)	
Median	51.39	37.96	42.59	23.15	
Min, Max	12.0, 89.8	0.9, 92.6	21.3, 79.6	11.1, 31.5	
C7D1 CFB					
n	47	101	10	6	
LS Mean (StdErr) [2]	-7.63 (2.828)	-16.42 (2.019)	-9.24 (5.912)	-43.75 (8.549)	
95% CI [2]	-13.22, -2.04	-20.41, -12.43	-22.12, 3.64	-62.38, -25.13	
Difference (95% CI) in CFB [2]		-8.79 (-14.77, -2.81)		-34.51 (-49.05, -19.98)	
Hedges'G (95% CI) in CFB		-0.44 (-0.80, -0.09)		-1.67 (-3.26, -0.64)	
p-value [3]		0.004		<0.001	
					0.018

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-age-a.sas Date: 15:52/07AUG2023

Table 35.2.8.2.1a
Change from Baseline in MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	54	113	11	6	
Mean (StdDev)	66.92 (17.126)	67.13 (14.972)	51.01 (15.776)	66.20 (10.455)	
Median	66.67	69.44	52.78	62.50	
Min, Max	13.9, 100.0	33.3, 97.2	30.6, 72.2	55.6, 80.6	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-age-a.sas Date: 15:52/07AUG2023

Table 35.2.8.2.1a
Change from Baseline in MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	54	113	11	6	
Mean (StdDev)	57.79 (18.980)	53.59 (18.560)	45.20 (13.152)	51.39 (14.567)	
Median	58.33	55.56	41.67	54.17	
Min, Max	11.1, 100.0	11.1, 94.4	27.8, 66.7	25.0, 69.4	
C2D1 CFB					
n	52	110	11	6	
LS Mean (StdErr) [2]	-8.13 (2.179)	-12.78 (1.610)	-12.44 (6.446)	-24.56 (9.398)	
95% CI [2]	-12.44, -3.83	-15.96, -9.60	-26.36, 1.49	-44.86, -4.26	
Difference (95% CI) in CFB [2]		-4.65 (-9.32, 0.02)		-12.12 (-27.92, 3.67)	
p-value [3]		0.051		0.121	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.1a
Change from Baseline in MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	53	104	10	6	
Mean (StdDev)	57.18 (21.650)	50.36 (20.294)	44.17 (16.483)	41.20 (11.708)	
Median	58.33	48.61	37.50	44.44	
Min, Max	11.1, 100.0	5.6, 95.8	27.8, 69.4	22.2, 55.6	
C3D1 CFB					
n	51	103	10	6	
LS Mean (StdErr) [2]	-9.26 (2.558)	-15.67 (1.872)	-8.63 (5.796)	-29.44 (8.380)	
95% CI [2]	-14.31, -4.20	-19.37, -11.97	-21.26, 3.99	-47.70, -11.18	
Difference (95% CI) in CFB [2]		-6.41 (-11.89, -0.93)		-20.81 (-35.05, -6.56)	
p-value [3]		0.022		0.008	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.1a
Change from Baseline in MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	49	107	7	6	
Mean (StdDev)	57.31 (22.897)	51.40 (21.060)	50.40 (16.929)	33.80 (13.078)	
Median	61.11	50.00	44.44	33.33	
Min, Max	11.1, 97.2	8.3, 94.4	27.8, 77.8	13.9, 52.8	
C4D1 CFB					
n	47	105	7	6	
LS Mean (StdErr) [2]	-9.56 (2.795)	-14.87 (2.021)	-2.31 (7.973)	-35.65 (13.078)	
95% CI [2]	-15.08, -4.03	-18.86, -10.88	-20.35, 15.72	-65.23, -6.06	
Difference (95% CI) in CFB [2]		-5.31 (-11.16, 0.53)		-33.33 (-59.02, -7.65)	
p-value [3]		0.075		0.017	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.1a
Change from Baseline in MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	51	103	9	5	
Mean (StdDev)	56.32 (22.912)	49.88 (20.998)	55.86 (15.741)	27.22 (12.329)	
Median	61.11	50.00	47.22	30.56	
Min, Max	11.1, 94.4	8.3, 100.0	41.7, 83.3	8.3, 38.9	
C5D1 CFB					
n	50	99	9	5	
LS Mean (StdErr) [2]	-10.22 (2.649)	-17.62 (1.971)	-1.75 (9.071)	-43.90 (13.930)	
95% CI [2]	-15.45, -4.98	-21.52, -13.73	-21.96, 18.46	-74.94, -12.86	
Difference (95% CI) in CFB [2]		-7.40 (-13.07, -1.73)		-42.15 (-67.59, -16.71)	
p-value [3]		0.011		0.004	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.1a
Change from Baseline in MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	50	105	8	6	
Mean (StdDev)	57.67 (22.070)	47.57 (23.102)	50.00 (11.691)	30.56 (10.971)	
Median	55.56	47.22	50.00	26.39	
Min, Max	16.7, 97.2	2.8, 97.2	33.3, 63.9	19.4, 50.0	
C6D1 CFB					
n	49	101	8	6	
LS Mean (StdErr) [2]	-7.46 (2.938)	-18.18 (2.153)	-10.00 (6.192)	-42.27 (10.280)	
95% CI [2]	-13.26, -1.65	-22.44, -13.93	-23.79, 3.80	-65.18, -19.37	
Difference (95% CI) in CFB [2]		-10.72 (-17.01, -4.44)		-32.28 (-52.03, -12.53)	
p-value [3]		<0.001		0.005	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.1a
Change from Baseline in MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	48	105	10	6	
Mean (StdDev)	55.38 (22.173)	48.12 (23.104)	47.50 (13.637)	28.70 (5.172)	
Median	55.56	41.67	47.22	27.78	
Min, Max	13.9, 97.2	0.0, 100.0	25.0, 66.7	22.2, 36.1	
C7D1 CFB					
n	47	101	10	6	
LS Mean (StdErr) [2]	-8.37 (2.991)	-16.21 (2.136)	-8.90 (6.074)	-45.46 (8.783)	
95% CI [2]	-14.28, -2.46	-20.43, -11.99	-22.13, 4.34	-64.60, -26.32	
Difference (95% CI) in CFB [2]		-7.84 (-14.17, -1.52)		-36.56 (-51.50, -21.63)	
Hedges'G (95% CI) in CFB		-0.37 (-0.73, -0.02)		-1.72 (-3.33, -0.69)	
p-value [3]		0.015		<0.001	
					0.009

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.1a
Change from Baseline in MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	54	113	11	6	
Mean (StdDev)	56.86 (22.549)	57.57 (21.440)	52.53 (24.766)	52.78 (16.005)	
Median	58.33	58.33	47.22	58.33	
Min, Max	13.9, 97.2	5.6, 100.0	13.9, 94.4	33.3, 72.2	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.1a
Change from Baseline in MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	54	113	11	6	
Mean (StdDev)	49.13 (22.293)	44.99 (24.473)	42.68 (24.447)	37.96 (15.079)	
Median	52.78	44.44	33.33	40.28	
Min, Max	5.6, 91.7	0.0, 100.0	2.8, 88.9	19.4, 58.3	
C2D1 CFB					
n	52	110	11	6	
LS Mean (StdErr) [2]	-6.58 (2.448)	-11.69 (1.809)	-11.58 (5.035)	-20.79 (7.341)	
95% CI [2]	-11.41, -1.74	-15.27, -8.12	-22.45, -0.70	-36.65, -4.94	
Difference (95% CI) in CFB [2]		-5.12 (-10.36, 0.13)		-9.22 (-21.55, 3.12)	
p-value [3]		0.056		0.131	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.8.2.1a
Change from Baseline in MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	53	103	10	6	
Mean (StdDev)	49.79 (23.531)	41.83 (23.904)	41.67 (23.859)	17.59 (11.340)	
Median	47.22	41.67	37.50	19.44	
Min, Max	5.6, 88.9	0.0, 100.0	8.3, 88.9	0.0, 30.6	
C3D1 CFB					
n	51	103	10	6	
LS Mean (StdErr) [2]	-7.45 (2.704)	-15.16 (1.979)	-12.67 (6.124)	-43.59 (8.855)	
95% CI [2]	-12.80, -2.11	-19.07, -11.25	-26.02, 0.67	-62.89, -24.30	
Difference (95% CI) in CFB [2]		-7.71 (-13.50, -1.92)		-30.92 (-45.97, -15.87)	
p-value [3]		0.009		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.1a
Change from Baseline in MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	49	107	7	6	
Mean (StdDev)	47.51 (22.339)	41.95 (24.866)	45.24 (30.417)	25.46 (18.544)	
Median	47.22	38.89	36.11	25.00	
Min, Max	8.3, 88.9	0.0, 97.2	11.1, 94.4	5.6, 50.0	
C4D1 CFB					
n	47	105	7	6	
LS Mean (StdErr) [2]	-9.40 (3.018)	-15.95 (2.182)	-10.69 (8.099)	-29.58 (13.283)	
95% CI [2]	-15.37, -3.44	-20.26, -11.64	-29.01, 7.63	-59.63, 0.47	
Difference (95% CI) in CFB [2]		-6.55 (-12.86, -0.24)		-18.89 (-44.98, 7.20)	
p-value [3]		0.042		0.136	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.1a
Change from Baseline in MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	50	104	9	5	
Mean (StdDev)	45.89 (24.553)	40.10 (24.944)	46.60 (23.520)	15.56 (12.360)	
Median	47.22	38.89	41.67	13.89	
Min, Max	0.0, 94.4	0.0, 100.0	16.7, 83.3	0.0, 30.6	
C5D1 CFB					
n	49	100	9	5	
LS Mean (StdErr) [2]	-9.37 (3.127)	-17.99 (2.304)	-11.35 (12.773)	-44.08 (19.616)	
95% CI [2]	-15.55, -3.19	-22.54, -13.43	-39.81, 17.11	-87.79, -0.37	
Difference (95% CI) in CFB [2]		-8.62 (-15.31, -1.92)		-32.73 (-68.56, 3.10)	
p-value [3]		0.012		0.069	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.1a
Change from Baseline in MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	50	105	8	6	
Mean (StdDev)	50.28 (24.179)	39.23 (26.726)	45.83 (19.754)	15.74 (12.870)	
Median	50.00	36.11	38.89	13.89	
Min, Max	0.0, 94.4	0.0, 100.0	25.0, 86.1	0.0, 33.3	
C6D1 CFB					
n	49	101	8	6	
LS Mean (StdErr) [2]	-5.96 (3.275)	-18.68 (2.400)	-10.27 (7.380)	-38.71 (12.251)	
95% CI [2]	-12.43, 0.51	-23.42, -13.94	-26.71, 6.17	-66.01, -11.41	
Difference (95% CI) in CFB [2]		-12.72 (-19.72, -5.72)		-28.44 (-51.98, -4.91)	
p-value [3]		<0.001		0.023	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.1a
Change from Baseline in MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	48	105	10	6	
Mean (StdDev)	47.45 (26.525)	37.91 (26.818)	43.33 (23.322)	15.28 (9.742)	
Median	47.22	33.33	43.06	13.89	
Min, Max	0.0, 97.2	0.0, 100.0	11.1, 88.9	2.8, 27.8	
C7D1 CFB					
n	47	101	10	6	
LS Mean (StdErr) [2]	-6.10 (3.440)	-16.56 (2.456)	-14.46 (8.081)	-50.90 (11.686)	
95% CI [2]	-12.90, 0.70	-21.42, -11.71	-32.07, 3.15	-76.36, -25.44	
Difference (95% CI) in CFB [2]		-10.46 (-17.74, -3.19)		-36.44 (-56.30, -16.57)	
Hedges'G (95% CI) in CFB		-0.43 (-0.79, -0.08)		-1.29 (-2.74, -0.28)	
p-value [3]		0.005		0.002	
					0.072

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-age-a.sas Date: 15:52/07AUG2023

Table 35.2.8.2.1a
Change from Baseline in MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	54	113	11	6	
Mean (StdDev)	50.49 (23.023)	51.11 (23.219)	49.62 (18.861)	57.64 (16.545)	
Median	50.00	50.00	54.17	60.42	
Min, Max	0.0, 100.0	0.0, 100.0	20.8, 79.2	29.2, 75.0	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.1a
Change from Baseline in MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	54	113	11	6	
Mean (StdDev)	42.67 (22.091)	39.53 (24.808)	42.80 (22.212)	47.22 (24.533)	
Median	41.67	33.33	45.83	43.75	
Min, Max	0.0, 91.7	0.0, 100.0	4.2, 83.3	20.8, 79.2	
C2D1 CFB					
n	52	110	11	6	
LS Mean (StdErr) [2]	-6.11 (2.389)	-10.81 (1.766)	-9.38 (6.560)	-13.54 (9.564)	
95% CI [2]	-10.83, -1.40	-14.30, -7.33	-23.55, 4.80	-34.20, 7.12	
Difference (95% CI) in CFB [2]		-4.70 (-9.82, 0.42)		-4.17 (-20.24, 11.91)	
p-value [3]		0.071		0.585	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.1a
Change from Baseline in MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	53	104	10	6	
Mean (StdDev)	40.86 (22.631)	35.50 (23.039)	45.42 (23.112)	27.78 (20.184)	
Median	37.50	33.33	47.92	33.33	
Min, Max	0.0, 87.5	0.0, 95.8	12.5, 91.7	0.0, 50.0	
C3D1 CFB					
n	51	103	10	6	
LS Mean (StdErr) [2]	-8.93 (2.660)	-15.13 (1.946)	-6.24 (6.249)	-31.43 (9.037)	
95% CI [2]	-14.19, -3.68	-18.97, -11.28	-19.85, 7.38	-51.12, -11.74	
Difference (95% CI) in CFB [2]		-6.20 (-11.89, -0.50)		-25.19 (-40.55, -9.83)	
p-value [3]		0.033		0.004	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.8.2.1a
Change from Baseline in MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	49	107	7	6	
Mean (StdDev)	40.82 (23.539)	35.69 (24.508)	57.14 (20.229)	30.56 (26.571)	
Median	41.67	33.33	54.17	33.33	
Min, Max	0.0, 83.3	0.0, 95.8	29.2, 91.7	0.0, 58.3	
C4D1 CFB					
n	47	105	7	6	
LS Mean (StdErr) [2]	-11.32 (2.974)	-17.57 (2.150)	-2.29 (9.538)	-33.13 (15.643)	
95% CI [2]	-17.20, -5.44	-21.81, -13.32	-23.87, 19.28	-68.51, 2.26	
Difference (95% CI) in CFB [2]		-6.25 (-12.47, -0.03)		-30.83 (-61.56, -0.11)	
p-value [3]		0.049		0.049	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.1a
Change from Baseline in MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	51	104	9	5	
Mean (StdDev)	38.40 (23.897)	33.01 (24.658)	49.54 (23.427)	22.50 (19.003)	
Median	37.50	25.00	58.33	20.83	
Min, Max	0.0, 95.8	0.0, 91.7	4.2, 70.8	0.0, 41.7	
C5D1 CFB					
n	50	100	9	5	
LS Mean (StdErr) [2]	-12.62 (3.099)	-20.08 (2.293)	-5.53 (9.230)	-32.34 (14.174)	
95% CI [2]	-18.74, -6.49	-24.61, -15.55	-26.09, 15.04	-63.92, -0.75	
Difference (95% CI) in CFB [2]		-7.46 (-14.08, -0.84)		-26.81 (-52.70, -0.92)	
p-value [3]		0.028		0.044	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.1a
Change from Baseline in MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	50	105	8	6	
Mean (StdDev)	41.08 (24.958)	32.62 (24.862)	48.96 (21.099)	22.22 (11.686)	
Median	37.50	29.17	45.83	20.83	
Min, Max	0.0, 100.0	0.0, 95.8	25.0, 79.2	8.3, 37.5	
C6D1 CFB					
n	49	101	8	6	
LS Mean (StdErr) [2]	-9.55 (3.267)	-20.29 (2.394)	-8.83 (6.011)	-43.52 (9.979)	
95% CI [2]	-16.01, -3.09	-25.02, -15.56	-22.23, 4.56	-65.75, -21.28	
Difference (95% CI) in CFB [2]		-10.74 (-17.73, -3.76)		-34.68 (-53.85, -15.51)	
p-value [3]		0.003		0.002	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.1a
Change from Baseline in MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	48	105	10	6	
Mean (StdDev)	38.37 (25.828)	32.10 (26.872)	45.00 (24.280)	24.31 (18.711)	
Median	33.33	25.00	43.75	22.92	
Min, Max	0.0, 100.0	0.0, 95.8	12.5, 79.2	4.2, 45.8	
C7D1 CFB					
n	47	101	10	6	
LS Mean (StdErr) [2]	-8.99 (3.444)	-16.81 (2.460)	-2.81 (7.148)	-30.20 (10.336)	
95% CI [2]	-15.80, -2.19	-21.67, -11.95	-18.38, 12.77	-52.72, -7.68	
Difference (95% CI) in CFB [2]		-7.82 (-15.10, -0.54)		-27.40 (-44.97, -9.83)	
Hedges'G (95% CI) in CFB		-0.32 (-0.67, 0.03)		-1.10 (-2.48, -0.09)	
p-value [3]		0.036		0.005	
					0.082

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-age-a.sas Date: 15:52/07AUG2023

Table 35.2.8.2.1a
Change from Baseline in MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	54	113	11	6	
Mean (StdDev)	62.19 (22.762)	57.30 (21.712)	66.67 (21.082)	55.56 (29.659)	
Median	66.67	58.33	75.00	45.83	
Min, Max	0.0, 100.0	8.3, 100.0	33.3, 91.7	25.0, 100.0	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-age-a.sas Date: 15:52/07AUG2023

Table 35.2.8.2.1a
Change from Baseline in MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	54	113	11	6	
Mean (StdDev)	54.32 (20.903)	41.74 (18.483)	58.33 (20.069)	33.33 (20.412)	
Median	50.00	41.67	58.33	25.00	
Min, Max	0.0, 91.7	0.0, 83.3	25.0, 83.3	16.7, 66.7	
C2D1 CFB					
n	52	110	11	6	
LS Mean (StdErr) [2]	-5.16 (3.222)	-12.51 (2.381)	-12.52 (6.487)	-28.81 (9.458)	
95% CI [2]	-11.52, 1.21	-17.21, -7.81	-26.54, 1.49	-49.24, -8.38	
Difference (95% CI) in CFB [2]		-7.35 (-14.25, -0.45)		-16.29 (-32.18, -0.39)	
p-value [3]		0.037		0.045	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-age-a.sas Date: 15:52/07AUG2023

Table 35.2.8.2.1a
Change from Baseline in MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	53	104	10	6	
Mean (StdDev)	52.52 (23.261)	39.66 (20.029)	48.33 (19.165)	33.33 (11.785)	
Median	58.33	41.67	50.00	33.33	
Min, Max	0.0, 100.0	0.0, 91.7	25.0, 75.0	16.7, 50.0	
C3D1 CFB					
n	51	103	10	6	
LS Mean (StdErr) [2]	-6.96 (3.668)	-14.59 (2.684)	-19.88 (9.291)	-24.89 (13.435)	
95% CI [2]	-14.21, 0.28	-19.89, -9.29	-40.12, 0.36	-54.16, 4.38	
Difference (95% CI) in CFB [2]		-7.63 (-15.48, 0.23)		-5.01 (-27.85, 17.83)	
p-value [3]		0.057		0.641	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-age-a.sas Date: 15:52/07AUG2023

Table 35.2.8.2.1a
Change from Baseline in MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	49	107	7	6	
Mean (StdDev)	54.25 (23.269)	37.77 (21.054)	55.95 (22.420)	29.17 (15.590)	
Median	58.33	33.33	66.67	25.00	
Min, Max	0.0, 100.0	0.0, 100.0	25.0, 83.3	16.7, 58.3	
C4D1 CFB					
n	47	105	7	6	
LS Mean (StdErr) [2]	-5.93 (3.864)	-17.32 (2.794)	-10.83 (10.726)	-22.50 (17.592)	
95% CI [2]	-13.57, 1.71	-22.84, -11.80	-35.10, 13.43	-62.30, 17.30	
Difference (95% CI) in CFB [2]		-11.39 (-19.47, -3.31)		-11.67 (-46.22, 22.89)	
p-value [3]		0.006		0.465	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-age-a.sas Date: 15:52/07AUG2023

Table 35.2.8.2.1a
Change from Baseline in MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	51	103	9	5	
Mean (StdDev)	51.63 (25.167)	37.86 (20.538)	63.89 (29.167)	23.33 (6.972)	
Median	58.33	33.33	75.00	25.00	
Min, Max	0.0, 100.0	0.0, 100.0	25.0, 91.7	16.7, 33.3	
C5D1 CFB					
n	50	99	9	5	
LS Mean (StdErr) [2]	-7.15 (3.783)	-16.36 (2.815)	-10.51 (7.588)	-38.41 (11.653)	
95% CI [2]	-14.62, 0.33	-21.92, -10.79	-27.41, 6.40	-64.37, -12.44	
Difference (95% CI) in CFB [2]		-9.21 (-17.31, -1.11)		-27.90 (-49.18, -6.61)	
p-value [3]		0.026		0.015	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-age-a.sas Date: 15:52/07AUG2023

Table 35.2.8.2.1a
Change from Baseline in MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	50	105	8	6	
Mean (StdDev)	51.17 (24.398)	39.37 (23.011)	55.21 (29.188)	20.83 (15.590)	
Median	54.17	33.33	50.00	16.67	
Min, Max	0.0, 100.0	0.0, 91.7	16.7, 100.0	8.3, 50.0	
C6D1 CFB					
n	49	101	8	6	
LS Mean (StdErr) [2]	-7.93 (3.883)	-15.82 (2.845)	-9.86 (10.805)	-38.50 (17.938)	
95% CI [2]	-15.60, -0.25	-21.44, -10.20	-33.93, 14.22	-78.47, 1.47	
Difference (95% CI) in CFB [2]		-7.89 (-16.20, 0.41)		-28.64 (-63.10, 5.82)	
p-value [3]		0.062		0.094	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.1a
Change from Baseline in MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	48	105	10	6	
Mean (StdDev)	50.17 (23.601)	37.54 (21.375)	65.00 (22.153)	20.83 (8.740)	
Median	50.00	33.33	66.67	20.83	
Min, Max	0.0, 100.0	0.0, 91.7	33.3, 100.0	8.3, 33.3	
C7D1 CFB					
n	47	101	10	6	
LS Mean (StdErr) [2]	-7.70 (3.908)	-15.74 (2.790)	-7.49 (9.157)	-44.31 (13.240)	
95% CI [2]	-15.42, 0.02	-21.25, -10.22	-27.44, 12.46	-73.16, -15.46	
Difference (95% CI) in CFB [2]		-8.04 (-16.30, 0.22)		-36.82 (-59.33, -14.31)	
Hedges'G (95% CI) in CFB		-0.29 (-0.64, 0.06)		-1.15 (-2.55, -0.14)	
p-value [3]		0.056		0.004	
					0.099

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-age-a.sas Date: 15:52/07AUG2023

Table 35.2.8.2.2a
Change from Baseline in MC-QoL by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	14	32	51	87	
Mean (StdDev)	56.02 (17.291)	53.94 (12.624)	58.87 (17.020)	61.22 (15.998)	
Median	59.26	53.70	59.26	61.11	
Min, Max	26.9, 88.9	28.7, 84.3	22.2, 97.2	26.9, 98.1	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-sex-a.sas Date: 15:52/07AUG2023

Table 35.2.8.2.2a
Change from Baseline in MC-QoL by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	14	33	51	86	
Mean (StdDev)	48.41 (21.119)	44.36 (13.199)	50.63 (15.674)	46.85 (19.644)	
Median	46.76	43.52	52.78	45.83	
Min, Max	19.4, 92.6	25.0, 81.5	16.7, 90.7	14.8, 90.7	
C2D1 CFB					
n	13	31	50	85	
LS Mean (StdErr) [2]	-6.12 (2.871)	-8.70 (1.900)	-7.57 (2.037)	-13.70 (1.735)	
95% CI [2]	-11.92, -0.32	-12.54, -4.86	-11.60, -3.54	-17.13, -10.27	
Difference (95% CI) in CFB [2]		-2.58 (-8.89, 3.72)		-6.13 (-10.59, -1.67)	
p-value [3]		0.412		0.007	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-sex-a.sas Date: 15:52/07AUG2023

Table 35.2.8.2.2a
Change from Baseline in MC-QoL by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	28	48	81	
Mean (StdDev)	46.98 (24.113)	39.52 (15.252)	50.35 (17.814)	42.94 (19.905)	
Median	46.30	36.11	49.54	38.89	
Min, Max	10.2, 88.0	12.0, 77.8	15.7, 88.0	1.9, 93.5	
C3D1 CFB					
n	14	28	47	81	
LS Mean (StdErr) [2]	-8.09 (4.357)	-13.82 (3.059)	-7.49 (2.323)	-16.25 (1.915)	
95% CI [2]	-16.91, 0.73	-20.02, -7.63	-12.08, -2.89	-20.04, -12.46	
Difference (95% CI) in CFB [2]		-5.73 (-15.37, 3.91)		-8.77 (-13.82, -3.72)	
p-value [3]		0.237		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-sex-a.sas Date: 15:52/07AUG2023

Table 35.2.8.2.2a
Change from Baseline in MC-QoL by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	13	30	43	83	
Mean (StdDev)	50.00 (20.715)	38.89 (15.446)	50.17 (18.407)	43.86 (21.663)	
Median	56.48	36.57	47.22	42.59	
Min, Max	18.5, 80.6	7.4, 79.6	14.8, 87.0	2.8, 90.7	
C4D1 CFB					
n	12	29	42	82	
LS Mean (StdErr) [2]	-6.56 (4.430)	-15.20 (3.059)	-8.28 (2.669)	-16.54 (2.137)	
95% CI [2]	-15.54, 2.42	-21.40, -9.00	-13.57, -3.00	-20.77, -12.31	
Difference (95% CI) in CFB [2]		-8.64 (-18.24, 0.96)		-8.26 (-13.95, -2.57)	
p-value [3]		0.076		0.005	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-sex-a.sas Date: 15:52/07AUG2023

Table 35.2.8.2.2a
Change from Baseline in MC-QoL by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	31	45	77	
Mean (StdDev)	46.98 (24.691)	34.71 (14.511)	49.53 (18.571)	43.18 (22.011)	
Median	51.85	33.33	49.07	37.04	
Min, Max	10.2, 88.0	11.1, 79.6	13.0, 85.2	4.6, 93.5	
C5D1 CFB					
n	14	28	45	76	
LS Mean (StdErr) [2]	-8.30 (4.672)	-17.93 (3.302)	-7.73 (2.781)	-18.27 (2.326)	
95% CI [2]	-17.76, 1.15	-24.62, -11.25	-13.24, -2.22	-22.88, -13.66	
Difference (95% CI) in CFB [2]		-9.63 (-19.89, 0.63)		-10.54 (-16.66, -4.42)	
p-value [3]		0.065		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-sex-a.sas Date: 15:52/07AUG2023

Table 35.2.8.2.2a
Change from Baseline in MC-QoL by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	13	32	45	79	
Mean (StdDev)	52.35 (20.967)	34.29 (16.442)	50.02 (19.290)	41.74 (23.688)	
Median	54.63	33.80	48.15	38.89	
Min, Max	18.5, 89.8	9.3, 86.1	12.0, 87.0	2.8, 92.6	
C6D1 CFB					
n	12	29	45	78	
LS Mean (StdErr) [2]	-3.53 (5.150)	-19.55 (3.443)	-7.02 (2.884)	-18.75 (2.389)	
95% CI [2]	-13.97, 6.90	-26.53, -12.57	-12.73, -1.31	-23.48, -14.02	
Difference (95% CI) in CFB [2]		-16.02 (-27.24, -4.80)		-11.73 (-18.09, -5.37)	
p-value [3]		0.006		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-sex-a.sas Date: 15:52/07AUG2023

Table 35.2.8.2.2a
Change from Baseline in MC-QoL by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	14	34	44	77	
Mean (StdDev)	50.40 (21.051)	36.63 (17.222)	47.54 (20.843)	40.09 (24.321)	
Median	53.24	33.33	45.83	34.26	
Min, Max	18.5, 87.0	16.7, 89.8	12.0, 89.8	0.9, 92.6	
C7D1 CFB					
n	13	31	44	76	
LS Mean (StdErr) [2]	-3.68 (5.110)	-15.20 (3.342)	-7.19 (2.990)	-17.98 (2.464)	
95% CI [2]	-14.01, 6.65	-21.96, -8.45	-13.11, -1.26	-22.86, -13.10	
Difference (95% CI) in CFB [2]		-11.52 (-22.65, -0.40)		-10.79 (-17.23, -4.35)	
Hedges'G (95% CI) in CFB		-0.61 (-1.32, 0.04)		-0.51 (-0.90, -0.14)	
p-value [3]		0.043		0.001	
					0.909

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-sex-a.sas Date: 15:52/07AUG2023

Table 35.2.8.2.2a
Change from Baseline in MC-QoL by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	14	32	51	87	
Mean (StdDev)	60.71 (17.222)	64.41 (14.723)	65.20 (18.039)	68.07 (14.716)	
Median	61.11	65.28	66.67	69.44	
Min, Max	30.6, 88.9	33.3, 86.1	13.9, 100.0	36.1, 97.2	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-sex-a.sas Date: 15:52/07AUG2023

Table 35.2.8.2.2a
Change from Baseline in MC-QoL by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	14	33	51	86	
Mean (StdDev)	52.98 (21.993)	53.87 (14.893)	56.39 (17.806)	53.33 (19.573)	
Median	50.00	52.78	58.33	55.56	
Min, Max	25.0, 100.0	30.6, 88.9	11.1, 97.2	11.1, 94.4	
C2D1 CFB					
n	13	31	50	85	
LS Mean (StdErr) [2]	-7.78 (3.365)	-9.85 (2.227)	-8.02 (2.360)	-14.25 (2.010)	
95% CI [2]	-14.58, -0.98	-14.35, -5.35	-12.69, -3.35	-18.22, -10.27	
Difference (95% CI) in CFB [2]		-2.07 (-9.46, 5.31)		-6.22 (-11.39, -1.06)	
p-value [3]		0.574		0.018	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-sex-a.sas Date: 15:52/07AUG2023

Table 35.2.8.2.2a
Change from Baseline in MC-QoL by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	28	48	82	
Mean (StdDev)	50.93 (23.609)	49.31 (16.780)	56.42 (20.677)	50.05 (21.072)	
Median	50.00	44.44	55.56	48.61	
Min, Max	11.1, 88.9	19.4, 88.9	16.7, 100.0	5.6, 95.8	
C3D1 CFB					
n	14	28	47	81	
LS Mean (StdErr) [2]	-8.91 (4.370)	-14.19 (3.069)	-7.67 (2.705)	-16.21 (2.229)	
95% CI [2]	-17.75, -0.06	-20.40, -7.97	-13.03, -2.32	-20.63, -11.80	
Difference (95% CI) in CFB [2]		-5.28 (-14.95, 4.39)		-8.54 (-14.42, -2.66)	
p-value [3]		0.276		0.005	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-sex-a.sas Date: 15:52/07AUG2023

Table 35.2.8.2.2a
Change from Baseline in MC-QoL by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	13	30	43	83	
Mean (StdDev)	55.56 (21.784)	49.26 (17.476)	56.72 (22.609)	50.90 (22.282)	
Median	55.56	47.22	61.11	50.00	
Min, Max	25.0, 88.9	16.7, 94.4	11.1, 97.2	8.3, 91.7	
C4D1 CFB					
n	12	29	42	82	
LS Mean (StdErr) [2]	-5.12 (4.576)	-13.83 (3.159)	-8.41 (3.108)	-15.43 (2.489)	
95% CI [2]	-14.40, 4.15	-20.23, -7.43	-14.56, -2.25	-20.36, -10.51	
Difference (95% CI) in CFB [2]		-8.70 (-18.62, 1.21)		-7.03 (-13.66, -0.40)	
p-value [3]		0.083		0.038	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-sex-a.sas Date: 15:52/07AUG2023

Table 35.2.8.2.2a
Change from Baseline in MC-QoL by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	31	45	77	
Mean (StdDev)	52.59 (23.906)	44.00 (14.648)	57.48 (21.300)	50.78 (23.107)	
Median	50.00	44.44	61.11	50.00	
Min, Max	16.7, 91.7	22.2, 75.0	11.1, 94.4	8.3, 100.0	
C5D1 CFB					
n	14	28	45	76	
LS Mean (StdErr) [2]	-7.34 (4.552)	-19.17 (3.217)	-6.87 (3.057)	-17.25 (2.557)	
95% CI [2]	-16.56, 1.87	-25.68, -12.66	-12.93, -0.82	-22.31, -12.19	
Difference (95% CI) in CFB [2]		-11.83 (-21.83, -1.83)		-10.38 (-17.11, -3.65)	
p-value [3]		0.022		0.003	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-sex-a.sas Date: 15:52/07AUG2023

Table 35.2.8.2.2a
Change from Baseline in MC-QoL by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	13	32	45	79	
Mean (StdDev)	57.48 (21.913)	43.14 (17.369)	56.36 (21.027)	48.07 (24.767)	
Median	61.11	43.06	55.56	50.00	
Min, Max	22.2, 94.4	16.7, 88.9	16.7, 97.2	2.8, 97.2	
C6D1 CFB					
n	12	29	45	78	
LS Mean (StdErr) [2]	-2.22 (5.144)	-20.26 (3.439)	-6.96 (3.163)	-17.80 (2.621)	
95% CI [2]	-12.64, 8.20	-27.23, -13.29	-13.23, -0.70	-22.99, -12.61	
Difference (95% CI) in CFB [2]		-18.04 (-29.25, -6.83)		-10.84 (-17.82, -3.86)	
p-value [3]		0.002		0.003	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-sex-a.sas Date: 15:52/07AUG2023

Table 35.2.8.2.2a
Change from Baseline in MC-QoL by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	14	34	44	77	
Mean (StdDev)	54.17 (19.330)	46.16 (16.765)	53.98 (21.802)	47.47 (25.255)	
Median	55.56	41.67	54.17	41.67	
Min, Max	22.2, 80.6	25.0, 94.4	13.9, 97.2	0.0, 100.0	
C7D1 CFB					
n	13	31	44	76	
LS Mean (StdErr) [2]	-3.64 (4.734)	-15.24 (3.097)	-7.61 (3.295)	-17.79 (2.716)	
95% CI [2]	-13.20, 5.93	-21.50, -8.98	-14.14, -1.09	-23.17, -12.42	
Difference (95% CI) in CFB [2]		-11.60 (-21.91, -1.30)		-10.18 (-17.28, -3.09)	
Hedges'G (95% CI) in CFB		-0.66 (-1.38, -0.02)		-0.44 (-0.83, -0.07)	
p-value [3]		0.028		0.005	
					0.870

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-sex-a.sas Date: 15:52/07AUG2023

Table 35.2.8.2.2a
Change from Baseline in MC-QoL by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	14	32	51	87	
Mean (StdDev)	54.17 (20.579)	51.22 (16.962)	56.67 (23.528)	59.58 (22.189)	
Median	54.17	52.78	55.56	61.11	
Min, Max	16.7, 91.7	19.4, 88.9	13.9, 97.2	5.6, 100.0	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-sex-a.sas Date: 15:52/07AUG2023

Table 35.2.8.2.2a
Change from Baseline in MC-QoL by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	14	33	51	86	
Mean (StdDev)	44.05 (24.866)	41.92 (16.657)	49.13 (22.079)	45.67 (26.409)	
Median	45.83	36.11	50.00	44.44	
Min, Max	5.6, 91.7	13.9, 86.1	2.8, 91.7	0.0, 100.0	
C2D1 CFB					
n	13	31	50	85	
LS Mean (StdErr) [2]	-8.03 (4.292)	-8.70 (2.840)	-7.22 (2.533)	-13.46 (2.157)	
95% CI [2]	-16.70, 0.65	-14.44, -2.95	-12.23, -2.21	-17.72, -9.19	
Difference (95% CI) in CFB [2]		-0.67 (-10.09, 8.75)		-6.24 (-11.78, -0.70)	
p-value [3]		0.887		0.028	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-sex-a.sas Date: 15:52/07AUG2023

Table 35.2.8.2.2a
Change from Baseline in MC-QoL by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	28	48	81	
Mean (StdDev)	46.85 (28.979)	37.70 (19.443)	49.02 (21.958)	41.46 (25.435)	
Median	47.22	36.11	45.83	41.67	
Min, Max	5.6, 88.9	2.8, 83.3	5.6, 88.9	0.0, 100.0	
C3D1 CFB					
n	14	28	47	81	
LS Mean (StdErr) [2]	-6.90 (6.019)	-14.19 (4.227)	-6.95 (2.664)	-16.42 (2.196)	
95% CI [2]	-19.08, 5.29	-22.75, -5.63	-12.22, -1.68	-20.77, -12.08	
Difference (95% CI) in CFB [2]		-7.29 (-20.61, 6.03)		-9.47 (-15.27, -3.68)	
p-value [3]		0.275		0.002	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-sex-a.sas Date: 15:52/07AUG2023

Table 35.2.8.2.2a
Change from Baseline in MC-QoL by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	13	30	43	83	
Mean (StdDev)	48.29 (22.411)	36.02 (16.530)	46.90 (23.650)	42.90 (27.013)	
Median	58.33	33.33	47.22	41.67	
Min, Max	19.4, 75.0	5.6, 69.4	8.3, 94.4	0.0, 97.2	
C4D1 CFB					
n	12	29	42	82	
LS Mean (StdErr) [2]	-6.94 (5.710)	-16.54 (3.942)	-8.81 (3.221)	-16.05 (2.579)	
95% CI [2]	-18.51, 4.62	-24.53, -8.55	-15.19, -2.44	-21.16, -10.95	
Difference (95% CI) in CFB [2]		-9.60 (-21.97, 2.77)		-7.24 (-14.11, -0.37)	
p-value [3]		0.124		0.039	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-sex-a.sas Date: 15:52/07AUG2023

Table 35.2.8.2.2a
Change from Baseline in MC-QoL by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	31	44	78	
Mean (StdDev)	45.00 (27.841)	32.17 (17.841)	46.34 (23.177)	41.68 (26.971)	
Median	47.22	36.11	45.83	41.67	
Min, Max	0.0, 91.7	2.8, 77.8	0.0, 94.4	0.0, 100.0	
C5D1 CFB					
n	14	28	44	77	
LS Mean (StdErr) [2]	-8.04 (6.274)	-18.76 (4.435)	-7.65 (3.379)	-18.08 (2.792)	
95% CI [2]	-20.74, 4.66	-27.74, -9.78	-14.34, -0.95	-23.61, -12.55	
Difference (95% CI) in CFB [2]		-10.72 (-24.50, 3.06)		-10.43 (-17.87, -3.00)	
p-value [3]		0.123		0.006	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-sex-a.sas Date: 15:52/07AUG2023

Table 35.2.8.2.2a
Change from Baseline in MC-QoL by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	13	32	45	79	
Mean (StdDev)	52.78 (24.349)	30.21 (19.601)	48.77 (23.470)	41.10 (28.562)	
Median	52.78	26.39	47.22	38.89	
Min, Max	11.1, 91.7	0.0, 80.6	0.0, 94.4	0.0, 100.0	
C6D1 CFB					
n	12	29	45	78	
LS Mean (StdErr) [2]	-1.63 (6.588)	-20.94 (4.405)	-6.17 (3.384)	-18.44 (2.804)	
95% CI [2]	-14.98, 11.72	-29.86, -12.01	-12.87, 0.53	-24.00, -12.89	
Difference (95% CI) in CFB [2]		-19.30 (-33.66, -4.94)		-12.28 (-19.74, -4.81)	
p-value [3]		0.010		0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-sex-a.sas Date: 15:52/07AUG2023

Table 35.2.8.2.2a
Change from Baseline in MC-QoL by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	14	34	44	77	
Mean (StdDev)	50.99 (26.768)	33.91 (20.318)	45.39 (25.725)	37.91 (29.059)	
Median	56.94	33.33	45.83	30.56	
Min, Max	8.3, 97.2	5.6, 80.6	0.0, 97.2	0.0, 100.0	
C7D1 CFB					
n	13	31	44	76	
LS Mean (StdErr) [2]	-1.91 (6.287)	-15.77 (4.113)	-6.32 (3.619)	-18.05 (2.983)	
95% CI [2]	-14.62, 10.79	-24.08, -7.46	-13.49, 0.85	-23.96, -12.14	
Difference (95% CI) in CFB [2]		-13.86 (-27.55, -0.17)		-11.73 (-19.53, -3.94)	
Hedges'G (95% CI) in CFB		-0.60 (-1.31, 0.05)		-0.46 (-0.85, -0.09)	
p-value [3]		0.047		0.004	
					0.759

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-sex-a.sas Date: 15:52/07AUG2023

Table 35.2.8.2.2a
Change from Baseline in MC-QoL by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	14	32	51	87	
Mean (StdDev)	45.24 (20.984)	44.14 (19.824)	51.75 (22.569)	54.12 (23.497)	
Median	45.83	41.67	50.00	54.17	
Min, Max	12.5, 83.3	0.0, 91.7	0.0, 100.0	8.3, 100.0	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-sex-a.sas Date: 15:52/07AUG2023

Table 35.2.8.2.2a
Change from Baseline in MC-QoL by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	14	33	51	86	
Mean (StdDev)	43.45 (21.291)	35.48 (17.681)	42.48 (22.314)	41.62 (26.870)	
Median	43.75	33.33	41.67	35.42	
Min, Max	12.5, 83.3	0.0, 70.8	0.0, 91.7	0.0, 100.0	
C2D1 CFB					
n	13	31	50	85	
LS Mean (StdErr) [2]	0.36 (3.313)	-7.82 (2.192)	-8.56 (2.586)	-12.28 (2.203)	
95% CI [2]	-6.34, 7.05	-12.25, -3.38	-13.68, -3.44	-16.63, -7.92	
Difference (95% CI) in CFB [2]		-8.17 (-15.45, -0.90)		-3.72 (-9.37, 1.94)	
p-value [3]		0.029		0.196	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-sex-a.sas Date: 15:52/07AUG2023

Table 35.2.8.2.2a
Change from Baseline in MC-QoL by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	28	48	82	
Mean (StdDev)	39.17 (25.579)	30.39 (19.098)	42.34 (21.802)	36.69 (23.926)	
Median	37.50	33.33	39.58	35.42	
Min, Max	0.0, 83.3	0.0, 79.2	0.0, 91.7	0.0, 95.8	
C3D1 CFB					
n	14	28	47	81	
LS Mean (StdErr) [2]	-4.82 (5.403)	-12.20 (3.794)	-8.75 (2.696)	-16.88 (2.222)	
95% CI [2]	-15.76, 6.11	-19.88, -4.52	-14.09, -3.42	-21.28, -12.48	
Difference (95% CI) in CFB [2]		-7.37 (-19.33, 4.59)		-8.12 (-13.99, -2.26)	
p-value [3]		0.220		0.007	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-sex-a.sas Date: 15:52/07AUG2023

Table 35.2.8.2.2a
Change from Baseline in MC-QoL by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	13	30	43	83	
Mean (StdDev)	40.71 (23.518)	30.28 (19.633)	43.51 (23.889)	37.28 (25.919)	
Median	45.83	29.17	45.83	37.50	
Min, Max	4.2, 83.3	0.0, 75.0	0.0, 91.7	0.0, 95.8	
C4D1 CFB					
n	12	29	42	82	
LS Mean (StdErr) [2]	-5.60 (5.146)	-14.42 (3.553)	-9.39 (3.284)	-18.43 (2.630)	
95% CI [2]	-16.03, 4.82	-21.62, -7.22	-15.89, -2.89	-23.64, -13.22	
Difference (95% CI) in CFB [2]		-8.82 (-19.97, 2.33)		-9.04 (-16.04, -2.04)	
p-value [3]		0.117		0.012	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-sex-a.sas Date: 15:52/07AUG2023

Table 35.2.8.2.2a
Change from Baseline in MC-QoL by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	31	45	78	
Mean (StdDev)	38.89 (28.810)	25.81 (18.048)	40.46 (22.484)	35.20 (26.203)	
Median	37.50	25.00	37.50	31.25	
Min, Max	0.0, 95.8	0.0, 87.5	0.0, 87.5	0.0, 91.7	
C5D1 CFB					
n	14	28	45	77	
LS Mean (StdErr) [2]	-7.66 (6.192)	-17.53 (4.377)	-11.14 (3.234)	-21.01 (2.683)	
95% CI [2]	-20.20, 4.87	-26.39, -8.67	-17.55, -4.74	-26.32, -15.70	
Difference (95% CI) in CFB [2]		-9.87 (-23.47, 3.74)		-9.87 (-16.97, -2.77)	
p-value [3]		0.150		0.007	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-sex-a.sas Date: 15:52/07AUG2023

Table 35.2.8.2.2a
Change from Baseline in MC-QoL by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	13	32	45	79	
Mean (StdDev)	42.31 (24.286)	28.26 (21.027)	42.13 (24.766)	33.60 (25.627)	
Median	54.17	25.00	37.50	33.33	
Min, Max	0.0, 79.2	0.0, 91.7	0.0, 100.0	0.0, 95.8	
C6D1 CFB					
n	12	29	45	78	
LS Mean (StdErr) [2]	-4.62 (5.949)	-18.56 (3.977)	-8.74 (3.455)	-21.53 (2.863)	
95% CI [2]	-16.67, 7.44	-26.62, -10.50	-15.58, -1.90	-27.20, -15.86	
Difference (95% CI) in CFB [2]		-13.94 (-26.91, -0.98)		-12.79 (-20.41, -5.17)	
p-value [3]		0.036		0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-sex-a.sas Date: 15:52/07AUG2023

Table 35.2.8.2.2a
Change from Baseline in MC-QoL by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	14	34	44	77	
Mean (StdDev)	39.88 (25.251)	27.57 (21.492)	39.39 (25.849)	33.50 (28.360)	
Median	33.33	20.83	35.42	29.17	
Min, Max	0.0, 83.3	0.0, 95.8	0.0, 100.0	0.0, 95.8	
C7D1 CFB					
n	13	31	44	76	
LS Mean (StdErr) [2]	-4.97 (6.361)	-16.00 (4.161)	-8.32 (3.551)	-17.72 (2.927)	
95% CI [2]	-17.82, 7.89	-24.41, -7.59	-15.35, -1.29	-23.52, -11.93	
Difference (95% CI) in CFB [2]		-11.03 (-24.88, 2.82)		-9.40 (-17.05, -1.75)	
Hedges'G (95% CI) in CFB		-0.47 (-1.17, 0.18)		-0.38 (-0.76, -0.01)	
p-value [3]		0.115		0.016	
					0.800

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-sex-a.sas Date: 15:52/07AUG2023

Table 35.2.8.2.2a
Change from Baseline in MC-QoL by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	14	32	51	87	
Mean (StdDev)	69.05 (15.821)	50.26 (23.426)	61.27 (23.736)	59.77 (21.044)	
Median	66.67	50.00	66.67	58.33	
Min, Max	50.0, 91.7	8.3, 100.0	0.0, 100.0	16.7, 100.0	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-sex-a.sas Date: 15:52/07AUG2023

Table 35.2.8.2.2a
Change from Baseline in MC-QoL by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	14	33	51	86	
Mean (StdDev)	57.74 (21.300)	40.91 (18.792)	54.25 (20.641)	41.47 (18.611)	
Median	54.17	41.67	50.00	41.67	
Min, Max	33.3, 91.7	8.3, 75.0	0.0, 91.7	0.0, 83.3	
C2D1 CFB					
n	13	31	50	85	
LS Mean (StdErr) [2]	-8.37 (4.589)	-7.06 (3.037)	-5.49 (3.439)	-15.28 (2.929)	
95% CI [2]	-17.65, 0.90	-13.20, -0.92	-12.29, 1.32	-21.08, -9.49	
Difference (95% CI) in CFB [2]		1.31 (-8.76, 11.39)		-9.80 (-17.32, -2.28)	
p-value [3]		0.793		0.011	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-sex-a.sas Date: 15:52/07AUG2023

Table 35.2.8.2.2a
Change from Baseline in MC-QoL by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	28	48	82	
Mean (StdDev)	51.11 (25.948)	33.63 (21.334)	52.08 (21.710)	41.26 (18.835)	
Median	58.33	25.00	54.17	41.67	
Min, Max	8.3, 91.7	0.0, 91.7	0.0, 100.0	0.0, 83.3	
C3D1 CFB					
n	14	28	47	81	
LS Mean (StdErr) [2]	-15.67 (6.485)	-15.06 (4.554)	-6.46 (3.848)	-14.43 (3.171)	
95% CI [2]	-28.79, -2.54	-24.28, -5.84	-14.08, 1.15	-20.71, -8.15	
Difference (95% CI) in CFB [2]		0.61 (-13.75, 14.96)		-7.97 (-16.33, 0.40)	
p-value [3]		0.932		0.062	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-sex-a.sas Date: 15:52/07AUG2023

Table 35.2.8.2.2a
Change from Baseline in MC-QoL by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	13	30	43	83	
Mean (StdDev)	57.05 (26.319)	33.61 (18.110)	53.68 (22.145)	38.65 (21.683)	
Median	58.33	25.00	58.33	33.33	
Min, Max	16.7, 100.0	0.0, 75.0	0.0, 100.0	0.0, 100.0	
C4D1 CFB					
n	12	29	42	82	
LS Mean (StdErr) [2]	-11.64 (7.237)	-16.83 (4.997)	-4.54 (4.070)	-17.41 (3.259)	
95% CI [2]	-26.30, 3.03	-26.96, -6.70	-12.60, 3.51	-23.86, -10.96	
Difference (95% CI) in CFB [2]		-5.19 (-20.87, 10.49)		-12.87 (-21.55, -4.19)	
p-value [3]		0.506		0.004	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-sex-a.sas Date: 15:52/07AUG2023

Table 35.2.8.2.2a
Change from Baseline in MC-QoL by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	31	45	77	
Mean (StdDev)	52.22 (24.289)	32.26 (15.920)	53.89 (26.686)	39.18 (21.632)	
Median	58.33	33.33	58.33	33.33	
Min, Max	16.7, 100.0	0.0, 83.3	0.0, 100.0	8.3, 100.0	
C5D1 CFB					
n	14	28	45	76	
LS Mean (StdErr) [2]	-13.26 (6.277)	-12.54 (4.437)	-3.96 (3.977)	-17.72 (3.327)	
95% CI [2]	-25.97, -0.55	-21.52, -3.56	-11.83, 3.92	-24.31, -11.14	
Difference (95% CI) in CFB [2]		0.72 (-13.07, 14.51)		-13.77 (-22.52, -5.01)	
p-value [3]		0.917		0.002	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-sex-a.sas Date: 15:52/07AUG2023

Table 35.2.8.2.2a
Change from Baseline in MC-QoL by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	13	32	45	79	
Mean (StdDev)	55.77 (20.521)	32.03 (19.296)	50.56 (26.075)	40.93 (23.989)	
Median	58.33	25.00	50.00	33.33	
Min, Max	25.0, 91.7	0.0, 83.3	0.0, 100.0	0.0, 91.7	
C6D1 CFB					
n	12	29	45	78	
LS Mean (StdErr) [2]	-10.97 (7.552)	-15.25 (5.049)	-6.73 (4.052)	-16.76 (3.357)	
95% CI [2]	-26.27, 4.33	-25.48, -5.02	-14.76, 1.29	-23.41, -10.12	
Difference (95% CI) in CFB [2]		-4.28 (-20.74, 12.18)		-10.03 (-18.97, -1.09)	
p-value [3]		0.601		0.028	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-sex-a.sas Date: 15:52/07AUG2023

Table 35.2.8.2.2a
Change from Baseline in MC-QoL by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	14	34	44	77	
Mean (StdDev)	58.33 (18.490)	34.31 (20.181)	50.95 (25.239)	37.66 (21.697)	
Median	58.33	25.00	50.00	33.33	
Min, Max	25.0, 91.7	8.3, 91.7	0.0, 100.0	0.0, 91.7	
C7D1 CFB					
n	13	31	44	76	
LS Mean (StdErr) [2]	-6.52 (7.549)	-11.78 (4.938)	-6.68 (3.986)	-18.66 (3.285)	
95% CI [2]	-21.78, 8.73	-21.76, -1.80	-14.58, 1.21	-25.17, -12.15	
Difference (95% CI) in CFB [2]		-5.25 (-21.69, 11.18)		-11.97 (-20.56, -3.39)	
Hedges'G (95% CI) in CFB		-0.19 (-0.87, 0.47)		-0.43 (-0.81, -0.06)	
p-value [3]		0.522		0.007	
					0.415

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-sex-a.sas Date: 15:52/07AUG2023

Table 35.2.8.2.3a
Change from Baseline in MC-QoL by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	30	49	35	70	
Mean (StdDev)	54.74 (19.504)	57.84 (16.220)	61.27 (14.079)	60.25 (14.937)	
Median	51.39	57.41	62.96	59.26	
Min, Max	22.2, 97.2	26.9, 87.0	27.8, 83.3	29.6, 98.1	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-reg-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.3a
Change from Baseline in MC-QoL by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	30	51	35	68	
Mean (StdDev)	47.84 (18.934)	43.71 (17.940)	52.14 (14.792)	48.00 (18.077)	
Median	43.06	42.59	52.78	47.22	
Min, Max	19.4, 92.6	15.7, 88.9	16.7, 82.4	14.8, 90.7	
C2D1 CFB					
n	28	48	35	68	
LS Mean (StdErr) [2]	-6.57 (2.734)	-14.47 (2.276)	-7.71 (2.155)	-10.68 (1.665)	
95% CI [2]	-12.02, -1.12	-19.01, -9.93	-11.99, -3.44	-13.98, -7.37	
Difference (95% CI) in CFB [2]		-7.90 (-13.94, -1.86)		-2.96 (-7.66, 1.73)	
p-value [3]		0.011		0.214	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-reg-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.3a
Change from Baseline in MC-QoL by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	29	43	34	66	
Mean (StdDev)	47.07 (20.274)	41.75 (19.221)	51.66 (18.542)	42.26 (18.687)	
Median	47.22	38.89	52.78	37.96	
Min, Max	10.2, 88.0	10.2, 88.0	16.7, 86.1	1.9, 93.5	
C3D1 CFB					
n	27	43	34	66	
LS Mean (StdErr) [2]	-6.84 (3.187)	-14.20 (2.682)	-8.43 (2.612)	-16.94 (1.969)	
95% CI [2]	-13.20, -0.48	-19.56, -8.85	-13.61, -3.24	-20.84, -13.03	
Difference (95% CI) in CFB [2]		-7.37 (-14.41, -0.32)		-8.51 (-14.20, -2.82)	
p-value [3]		0.041		0.004	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-reg-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.3a
Change from Baseline in MC-QoL by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	22	44	34	69	
Mean (StdDev)	46.97 (21.259)	38.95 (18.330)	52.18 (16.991)	44.82 (21.203)	
Median	43.06	35.65	56.02	42.59	
Min, Max	14.8, 80.6	9.3, 86.1	18.5, 87.0	2.8, 90.7	
C4D1 CFB					
n	20	43	34	68	
LS Mean (StdErr) [2]	-10.36 (3.727)	-20.20 (2.989)	-7.56 (2.835)	-14.75 (2.134)	
95% CI [2]	-17.82, -2.90	-26.18, -14.22	-13.18, -1.93	-18.99, -10.52	
Difference (95% CI) in CFB [2]		-9.84 (-17.57, -2.11)		-7.19 (-13.34, -1.04)	
p-value [3]		0.014		0.022	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-reg-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.3a
Change from Baseline in MC-QoL by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	26	40	34	68	
Mean (StdDev)	43.27 (22.325)	39.35 (19.349)	53.19 (17.297)	41.57 (21.160)	
Median	40.74	35.19	53.70	36.57	
Min, Max	10.2, 85.2	13.9, 93.5	16.7, 88.0	4.6, 86.1	
C5D1 CFB					
n	25	37	34	67	
LS Mean (StdErr) [2]	-11.53 (3.697)	-19.67 (3.179)	-5.90 (3.098)	-17.72 (2.350)	
95% CI [2]	-18.93, -4.13	-26.04, -13.31	-12.05, 0.25	-22.39, -13.06	
Difference (95% CI) in CFB [2]		-8.15 (-16.45, 0.16)		-11.82 (-18.56, -5.08)	
p-value [3]		0.054		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.3a
Change from Baseline in MC-QoL by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	24	44	34	67	
Mean (StdDev)	47.26 (21.772)	33.67 (19.817)	52.86 (17.717)	43.48 (22.687)	
Median	44.91	28.24	53.24	40.74	
Min, Max	12.0, 89.8	7.4, 92.6	15.7, 83.3	2.8, 92.6	
C6D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-8.30 (3.808)	-25.41 (3.157)	-5.96 (3.182)	-15.63 (2.398)	
95% CI [2]	-15.92, -0.68	-31.72, -19.10	-12.28, 0.35	-20.39, -10.87	
Difference (95% CI) in CFB [2]		-17.11 (-25.57, -8.65)		-9.66 (-16.60, -2.73)	
p-value [3]		<0.001		0.007	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-reg-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.3a
Change from Baseline in MC-QoL by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	24	44	34	67	
Mean (StdDev)	42.05 (21.763)	33.99 (20.671)	52.59 (19.128)	42.34 (22.961)	
Median	41.67	26.39	52.78	41.67	
Min, Max	12.0, 85.2	8.3, 91.7	13.9, 89.8	0.9, 92.6	
C7D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-9.29 (4.001)	-21.62 (3.204)	-5.02 (3.329)	-14.85 (2.509)	
95% CI [2]	-17.29, -1.29	-28.03, -15.22	-11.63, 1.59	-19.83, -9.87	
Difference (95% CI) in CFB [2]		-12.34 (-20.76, -3.91)		-9.83 (-17.09, -2.58)	
Hedges'G (95% CI) in CFB		-0.61 (-1.16, -0.10)		-0.49 (-0.92, -0.07)	
p-value [3]		0.005		0.008	
					0.626

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-reg-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.3a
Change from Baseline in MC-QoL by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	30	49	35	70	
Mean (StdDev)	59.81 (20.173)	66.33 (15.781)	68.02 (14.812)	67.62 (14.068)	
Median	56.94	69.44	66.67	69.44	
Min, Max	13.9, 100.0	33.3, 94.4	33.3, 97.2	36.1, 97.2	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-reg-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.3a
Change from Baseline in MC-QoL by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	30	51	35	68	
Mean (StdDev)	52.81 (20.574)	51.81 (18.140)	58.10 (16.753)	54.74 (18.513)	
Median	52.78	52.78	58.33	55.56	
Min, Max	11.1, 100.0	11.1, 94.4	25.0, 97.2	19.4, 91.7	
C2D1 CFB					
n	28	48	35	68	
LS Mean (StdErr) [2]	-6.85 (3.274)	-14.45 (2.726)	-8.97 (2.398)	-12.05 (1.852)	
95% CI [2]	-13.37, -0.32	-19.88, -9.02	-13.72, -4.21	-15.73, -8.37	
Difference (95% CI) in CFB [2]		-7.60 (-14.83, -0.37)		-3.08 (-8.30, 2.14)	
p-value [3]		0.040		0.244	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.3a
Change from Baseline in MC-QoL by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	29	44	34	66	
Mean (StdDev)	52.20 (22.911)	50.66 (20.846)	57.60 (19.917)	49.33 (19.551)	
Median	55.56	48.61	56.94	44.44	
Min, Max	11.1, 100.0	5.6, 95.8	19.4, 97.2	5.6, 91.7	
C3D1 CFB					
n	27	43	34	66	
LS Mean (StdErr) [2]	-7.44 (3.598)	-15.29 (3.028)	-8.75 (2.985)	-16.49 (2.250)	
95% CI [2]	-14.63, -0.26	-21.33, -9.24	-14.68, -2.83	-20.96, -12.03	
Difference (95% CI) in CFB [2]		-7.84 (-15.79, 0.11)		-7.74 (-14.25, -1.24)	
p-value [3]		0.053		0.020	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.3a
Change from Baseline in MC-QoL by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	22	44	34	69	
Mean (StdDev)	53.91 (25.940)	47.79 (18.988)	58.09 (19.706)	52.17 (22.232)	
Median	51.39	45.83	61.11	52.78	
Min, Max	11.1, 94.4	8.3, 91.7	25.0, 97.2	8.3, 94.4	
C4D1 CFB					
n	20	43	34	68	
LS Mean (StdErr) [2]	-9.54 (4.536)	-19.16 (3.637)	-7.79 (3.135)	-13.67 (2.359)	
95% CI [2]	-18.61, -0.46	-26.44, -11.89	-14.01, -1.57	-18.35, -8.98	
Difference (95% CI) in CFB [2]		-9.63 (-19.04, -0.22)		-5.87 (-12.68, 0.93)	
p-value [3]		0.045		0.090	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.3a
Change from Baseline in MC-QoL by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	26	40	34	68	
Mean (StdDev)	50.75 (25.099)	48.68 (20.198)	60.47 (18.333)	48.92 (21.895)	
Median	47.22	44.44	63.89	50.00	
Min, Max	11.1, 91.7	16.7, 100.0	19.4, 94.4	8.3, 90.6	
C5D1 CFB					
n	25	37	34	67	
LS Mean (StdErr) [2]	-9.97 (3.962)	-18.69 (3.407)	-5.64 (3.329)	-17.64 (2.525)	
95% CI [2]	-17.90, -2.04	-25.51, -11.87	-12.24, 0.97	-22.65, -12.63	
Difference (95% CI) in CFB [2]		-8.72 (-17.62, 0.18)		-12.00 (-19.24, -4.76)	
p-value [3]		0.055		0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.3a
Change from Baseline in MC-QoL by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	24	44	34	67	
Mean (StdDev)	52.66 (23.676)	41.73 (19.582)	59.40 (18.828)	49.88 (24.463)	
Median	47.22	40.28	61.11	50.00	
Min, Max	16.7, 94.4	2.8, 97.2	22.2, 97.2	2.8, 94.4	
C6D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-8.59 (4.160)	-25.16 (3.448)	-5.36 (3.405)	-15.10 (2.566)	
95% CI [2]	-16.92, -0.27	-32.06, -18.27	-12.12, 1.39	-20.19, -10.00	
Difference (95% CI) in CFB [2]		-16.57 (-25.81, -7.32)		-9.73 (-17.15, -2.31)	
p-value [3]		<0.001		0.011	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.3a
Change from Baseline in MC-QoL by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	24	44	34	67	
Mean (StdDev)	46.88 (22.227)	42.36 (22.004)	59.07 (18.943)	50.17 (23.144)	
Median	48.61	36.11	56.94	52.78	
Min, Max	13.9, 83.3	13.9, 100.0	25.0, 97.2	0.0, 94.4	
C7D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-8.59 (4.466)	-21.98 (3.576)	-5.92 (3.407)	-14.33 (2.568)	
95% CI [2]	-17.53, 0.34	-29.13, -14.83	-12.68, 0.84	-19.42, -9.23	
Difference (95% CI) in CFB [2]		-13.38 (-22.79, -3.98)		-8.41 (-15.83, -0.98)	
Hedges'G (95% CI) in CFB		-0.59 (-1.14, -0.08)		-0.41 (-0.84, 0.01)	
p-value [3]		0.006		0.027	
					0.388

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-reg-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.3a
Change from Baseline in MC-QoL by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	30	49	35	70	
Mean (StdDev)	49.94 (23.817)	51.93 (21.630)	61.43 (20.774)	61.11 (20.148)	
Median	47.22	52.78	61.11	63.89	
Min, Max	13.9, 97.2	16.7, 94.4	13.9, 94.4	5.6, 100.0	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-reg-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.3a
Change from Baseline in MC-QoL by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	30	51	35	68	
Mean (StdDev)	42.41 (24.619)	39.38 (23.045)	52.86 (19.820)	48.57 (24.275)	
Median	33.33	36.11	55.56	50.00	
Min, Max	5.6, 91.7	0.0, 100.0	2.8, 88.9	5.6, 100.0	
C2D1 CFB					
n	28	48	35	68	
LS Mean (StdErr) [2]	-7.28 (3.474)	-13.46 (2.892)	-7.16 (2.805)	-10.93 (2.167)	
95% CI [2]	-14.20, -0.35	-19.22, -7.69	-12.72, -1.59	-15.23, -6.63	
Difference (95% CI) in CFB [2]		-6.18 (-13.85, 1.49)		-3.77 (-9.88, 2.34)	
p-value [3]		0.113		0.224	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.3a
Change from Baseline in MC-QoL by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	29	43	34	66	
Mean (StdDev)	44.44 (24.125)	37.47 (23.526)	51.96 (22.891)	42.47 (24.293)	
Median	38.89	33.33	55.56	41.67	
Min, Max	5.6, 88.9	2.8, 94.4	5.6, 88.9	0.0, 100.0	
C3D1 CFB					
n	27	43	34	66	
LS Mean (StdErr) [2]	-4.53 (3.755)	-12.16 (3.160)	-8.72 (3.189)	-18.51 (2.404)	
95% CI [2]	-12.03, 2.96	-18.47, -5.85	-15.05, -2.39	-23.28, -13.74	
Difference (95% CI) in CFB [2]		-7.63 (-15.93, 0.67)		-9.79 (-16.74, -2.84)	
p-value [3]		0.071		0.006	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.3a
Change from Baseline in MC-QoL by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	22	44	34	69	
Mean (StdDev)	42.05 (26.146)	33.71 (22.032)	50.57 (20.751)	45.77 (25.444)	
Median	31.94	31.94	50.00	47.22	
Min, Max	8.3, 88.9	0.0, 94.4	11.1, 94.4	0.0, 97.2	
C4D1 CFB					
n	20	43	34	68	
LS Mean (StdErr) [2]	-8.75 (4.876)	-19.24 (3.910)	-8.90 (3.371)	-14.77 (2.537)	
95% CI [2]	-18.51, 1.01	-27.06, -11.42	-15.59, -2.21	-19.80, -9.73	
Difference (95% CI) in CFB [2]		-10.49 (-20.60, -0.38)		-5.87 (-13.18, 1.44)	
p-value [3]		0.042		0.114	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.3a
Change from Baseline in MC-QoL by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	26	41	33	68	
Mean (StdDev)	37.61 (25.595)	34.62 (22.932)	52.61 (21.154)	41.61 (25.999)	
Median	38.89	30.56	50.00	41.67	
Min, Max	0.0, 83.3	2.8, 100.0	19.4, 94.4	0.0, 100.0	
C5D1 CFB					
n	25	38	33	67	
LS Mean (StdErr) [2]	-10.61 (4.557)	-18.81 (3.862)	-5.99 (3.912)	-18.29 (2.950)	
95% CI [2]	-19.73, -1.50	-26.54, -11.09	-13.75, 1.78	-24.15, -12.43	
Difference (95% CI) in CFB [2]		-8.20 (-18.35, 1.96)		-12.30 (-20.84, -3.77)	
p-value [3]		0.111		0.005	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-reg-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.3a
Change from Baseline in MC-QoL by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	24	44	34	67	
Mean (StdDev)	44.44 (25.327)	28.47 (23.495)	53.35 (21.773)	44.20 (26.952)	
Median	43.06	23.61	54.17	44.44	
Min, Max	0.0, 91.7	0.0, 100.0	11.1, 94.4	0.0, 100.0	
C6D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-6.19 (4.554)	-24.85 (3.775)	-5.67 (3.875)	-16.21 (2.921)	
95% CI [2]	-15.30, 2.92	-32.40, -17.30	-13.36, 2.03	-22.00, -10.41	
Difference (95% CI) in CFB [2]		-18.66 (-28.78, -8.54)		-10.54 (-18.98, -2.09)	
p-value [3]		<0.001		0.015	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.3a
Change from Baseline in MC-QoL by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	24	44	34	67	
Mean (StdDev)	38.66 (26.185)	28.66 (24.237)	52.45 (24.406)	41.96 (27.032)	
Median	34.72	22.22	55.56	41.67	
Min, Max	2.8, 91.7	0.0, 100.0	0.0, 97.2	0.0, 100.0	
C7D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-7.11 (4.680)	-20.66 (3.748)	-4.64 (4.180)	-15.78 (3.150)	
95% CI [2]	-16.48, 2.25	-28.16, -13.16	-12.94, 3.66	-22.03, -9.52	
Difference (95% CI) in CFB [2]		-13.55 (-23.40, -3.69)		-11.14 (-20.24, -2.03)	
Hedges'G (95% CI) in CFB		-0.57 (-1.12, -0.06)		-0.44 (-0.87, -0.03)	
p-value [3]		0.008		0.017	
					0.701

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.3a
Change from Baseline in MC-QoL by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	30	49	35	70	
Mean (StdDev)	50.06 (25.743)	54.08 (22.575)	50.60 (19.125)	49.58 (23.141)	
Median	47.92	50.00	50.00	50.00	
Min, Max	0.0, 100.0	8.3, 100.0	20.8, 87.5	0.0, 100.0	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.3a
Change from Baseline in MC-QoL by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	30	51	35	68	
Mean (StdDev)	44.03 (24.582)	40.36 (23.957)	41.55 (19.686)	39.58 (25.498)	
Median	41.67	33.33	45.83	35.42	
Min, Max	0.0, 91.7	4.2, 100.0	4.2, 75.0	0.0, 100.0	
C2D1 CFB					
n	28	48	35	68	
LS Mean (StdErr) [2]	-4.82 (3.181)	-14.44 (2.648)	-8.03 (2.865)	-8.47 (2.214)	
95% CI [2]	-11.16, 1.52	-19.71, -9.16	-13.72, -2.35	-12.86, -4.08	
Difference (95% CI) in CFB [2]		-9.61 (-16.64, -2.59)		-0.44 (-6.68, 5.80)	
p-value [3]		0.008		0.890	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.3a
Change from Baseline in MC-QoL by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	29	44	34	66	
Mean (StdDev)	40.20 (22.527)	39.11 (22.931)	42.77 (22.898)	32.40 (22.616)	
Median	37.50	37.50	39.58	33.33	
Min, Max	0.0, 83.3	0.0, 95.8	0.0, 91.7	0.0, 95.8	
C3D1 CFB					
n	27	43	34	66	
LS Mean (StdErr) [2]	-8.53 (3.897)	-14.36 (3.279)	-7.27 (3.011)	-16.60 (2.270)	
95% CI [2]	-16.31, -0.75	-20.91, -7.81	-13.25, -1.30	-21.11, -12.10	
Difference (95% CI) in CFB [2]		-5.83 (-14.44, 2.78)		-9.33 (-15.89, -2.76)	
p-value [3]		0.181		0.006	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.3a
Change from Baseline in MC-QoL by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	22	44	34	69	
Mean (StdDev)	38.45 (22.964)	35.51 (22.564)	45.71 (23.935)	35.36 (25.854)	
Median	37.50	31.25	45.83	33.33	
Min, Max	0.0, 83.3	0.0, 95.8	0.0, 91.7	0.0, 95.8	
C4D1 CFB					
n	20	43	34	68	
LS Mean (StdErr) [2]	-15.42 (4.335)	-21.53 (3.476)	-5.84 (3.540)	-16.09 (2.664)	
95% CI [2]	-24.09, -6.74	-28.48, -14.57	-12.86, 1.19	-21.38, -10.81	
Difference (95% CI) in CFB [2]		-6.11 (-15.10, 2.88)		-10.26 (-17.94, -2.57)	
p-value [3]		0.179		0.009	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.3a
Change from Baseline in MC-QoL by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	26	41	34	68	
Mean (StdDev)	35.26 (24.783)	33.13 (23.048)	43.75 (23.011)	32.17 (25.430)	
Median	37.50	25.00	45.83	25.00	
Min, Max	0.0, 87.5	0.0, 91.7	0.0, 95.8	0.0, 91.7	
C5D1 CFB					
n	25	38	34	67	
LS Mean (StdErr) [2]	-16.77 (4.393)	-23.50 (3.723)	-6.42 (3.708)	-18.59 (2.813)	
95% CI [2]	-25.56, -7.98	-30.95, -16.05	-13.78, 0.94	-24.18, -13.01	
Difference (95% CI) in CFB [2]		-6.73 (-16.52, 3.06)		-12.17 (-20.24, -4.11)	
p-value [3]		0.174		0.003	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.3a
Change from Baseline in MC-QoL by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	24	44	34	67	
Mean (StdDev)	40.28 (24.347)	28.98 (23.032)	43.50 (24.793)	34.08 (25.250)	
Median	37.50	20.83	37.50	33.33	
Min, Max	0.0, 91.7	0.0, 83.3	0.0, 100.0	0.0, 95.8	
C6D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-11.50 (4.623)	-27.96 (3.832)	-6.33 (3.798)	-16.80 (2.862)	
95% CI [2]	-20.74, -2.25	-35.63, -20.30	-13.86, 1.21	-22.49, -11.12	
Difference (95% CI) in CFB [2]		-16.47 (-26.74, -6.19)		-10.48 (-18.75, -2.20)	
p-value [3]		0.002		0.014	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.3a
Change from Baseline in MC-QoL by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	24	44	34	67	
Mean (StdDev)	34.72 (23.719)	29.92 (24.416)	42.89 (26.482)	32.84 (27.890)	
Median	29.17	22.92	37.50	29.17	
Min, Max	0.0, 87.5	0.0, 91.7	0.0, 100.0	0.0, 95.8	
C7D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-12.71 (4.559)	-21.42 (3.650)	-5.13 (4.097)	-15.41 (3.087)	
95% CI [2]	-21.83, -3.59	-28.73, -14.12	-13.27, 3.00	-21.54, -9.28	
Difference (95% CI) in CFB [2]		-8.71 (-18.31, 0.89)		-10.28 (-19.20, -1.35)	
Hedges'G (95% CI) in CFB		-0.38 (-0.92, 0.14)		-0.41 (-0.85, 0.00)	
p-value [3]		0.075		0.024	
					0.855

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-reg-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.3a
Change from Baseline in MC-QoL by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	30	49	35	70	
Mean (StdDev)	64.17 (23.279)	57.65 (23.560)	61.90 (21.889)	56.90 (21.042)	
Median	70.83	58.33	66.67	58.33	
Min, Max	16.7, 100.0	16.7, 100.0	0.0, 91.7	8.3, 100.0	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-reg-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.3a
Change from Baseline in MC-QoL by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	30	51	35	68	
Mean (StdDev)	56.94 (19.706)	39.22 (20.364)	53.33 (21.599)	42.89 (17.112)	
Median	58.33	33.33	50.00	41.67	
Min, Max	16.7, 91.7	0.0, 83.3	0.0, 91.7	0.0, 83.3	
C2D1 CFB					
n	28	48	35	68	
LS Mean (StdErr) [2]	-7.58 (4.730)	-17.13 (3.937)	-4.99 (3.550)	-10.21 (2.743)	
95% CI [2]	-17.01, 1.85	-24.98, -9.28	-12.03, 2.06	-15.65, -4.77	
Difference (95% CI) in CFB [2]		-9.55 (-19.99, 0.89)		-5.22 (-12.95, 2.51)	
p-value [3]		0.072		0.184	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.3a
Change from Baseline in MC-QoL by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	29	44	34	66	
Mean (StdDev)	53.16 (20.463)	38.26 (20.358)	50.74 (24.478)	40.03 (19.349)	
Median	58.33	33.33	50.00	41.67	
Min, Max	16.7, 91.7	0.0, 91.7	0.0, 100.0	0.0, 83.3	
C3D1 CFB					
n	27	43	34	66	
LS Mean (StdErr) [2]	-9.38 (5.200)	-16.52 (4.376)	-8.80 (4.288)	-14.25 (3.232)	
95% CI [2]	-19.76, 1.01	-25.25, -7.78	-17.31, -0.29	-20.66, -7.83	
Difference (95% CI) in CFB [2]		-7.14 (-18.63, 4.35)		-5.45 (-14.79, 3.90)	
p-value [3]		0.219		0.250	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.3a
Change from Baseline in MC-QoL by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	22	44	34	69	
Mean (StdDev)	57.95 (21.894)	35.04 (20.772)	52.21 (23.687)	38.77 (20.898)	
Median	58.33	33.33	54.17	33.33	
Min, Max	16.7, 100.0	0.0, 100.0	0.0, 100.0	0.0, 91.7	
C4D1 CFB					
n	20	43	34	68	
LS Mean (StdErr) [2]	-8.59 (5.818)	-23.19 (4.665)	-6.23 (4.428)	-15.31 (3.333)	
95% CI [2]	-20.23, 3.06	-32.53, -13.86	-15.02, 2.56	-21.92, -8.69	
Difference (95% CI) in CFB [2]		-14.60 (-26.67, -2.54)		-9.07 (-18.68, 0.54)	
p-value [3]		0.019		0.064	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.3a
Change from Baseline in MC-QoL by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	26	40	34	68	
Mean (StdDev)	53.85 (28.110)	35.42 (20.823)	53.19 (24.534)	38.24 (20.118)	
Median	54.17	33.33	58.33	33.33	
Min, Max	8.3, 100.0	0.0, 100.0	0.0, 91.7	8.3, 91.7	
C5D1 CFB					
n	25	37	34	67	
LS Mean (StdErr) [2]	-9.45 (5.244)	-20.08 (4.510)	-4.54 (4.503)	-14.78 (3.416)	
95% CI [2]	-19.95, 1.04	-29.11, -11.05	-13.48, 4.39	-21.56, -8.00	
Difference (95% CI) in CFB [2]		-10.63 (-22.41, 1.15)		-10.24 (-20.03, -0.44)	
p-value [3]		0.076		0.041	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.3a
Change from Baseline in MC-QoL by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	24	44	34	67	
Mean (StdDev)	53.47 (27.793)	34.47 (21.611)	50.49 (22.931)	40.92 (23.692)	
Median	58.33	33.33	50.00	33.33	
Min, Max	0.0, 100.0	0.0, 91.7	0.0, 100.0	0.0, 91.7	
C6D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-8.25 (5.533)	-22.42 (4.586)	-7.93 (4.597)	-13.15 (3.465)	
95% CI [2]	-19.32, 2.81	-31.59, -13.24	-17.06, 1.19	-20.02, -6.27	
Difference (95% CI) in CFB [2]		-14.16 (-26.46, -1.87)		-5.21 (-15.23, 4.81)	
p-value [3]		0.025		0.304	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-reg-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.3a
Change from Baseline in MC-QoL by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	24	44	34	67	
Mean (StdDev)	52.43 (28.070)	32.95 (18.412)	52.94 (20.809)	39.05 (22.670)	
Median	54.17	29.17	50.00	33.33	
Min, Max	0.0, 100.0	8.3, 83.3	0.0, 91.7	0.0, 91.7	
C7D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-11.96 (5.884)	-23.61 (4.711)	-3.23 (4.362)	-12.55 (3.287)	
95% CI [2]	-23.73, -0.20	-33.04, -14.19	-11.88, 5.43	-19.07, -6.02	
Difference (95% CI) in CFB [2]		-11.65 (-24.04, 0.74)		-9.32 (-18.83, 0.19)	
Hedges'G (95% CI) in CFB		-0.39 (-0.93, 0.12)		-0.35 (-0.78, 0.06)	
p-value [3]		0.065		0.055	
					0.729

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-reg-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.4a
Change from Baseline in MC-QoL by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.4a
Change from Baseline in MC-QoL by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-cou-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.4a
Change from Baseline in MC-QoL by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.4a
Change from Baseline in MC-QoL by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-cou-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.4a
Change from Baseline in MC-QoL by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-cou-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.4a
Change from Baseline in MC-QoL by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.8.2.4a
Change from Baseline in MC-QoL by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-cou-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.4a
Change from Baseline in MC-QoL by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.8.2.4a
Change from Baseline in MC-QoL by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.8.2.4a
Change from Baseline in MC-QoL by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.8.2.4a
Change from Baseline in MC-QoL by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.4a
Change from Baseline in MC-QoL by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.8.2.4a
Change from Baseline in MC-QoL by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.8.2.4a
Change from Baseline in MC-QoL by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.8.2.4a
Change from Baseline in MC-QoL by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.8.2.4a
Change from Baseline in MC-QoL by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.4a
Change from Baseline in MC-QoL by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions						
	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.8.2.4a
Change from Baseline in MC-QoL by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.8.2.4a
Change from Baseline in MC-QoL by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.8.2.4a
Change from Baseline in MC-QoL by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.8.2.4a
Change from Baseline in MC-QoL by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.8.2.4a
Change from Baseline in MC-QoL by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
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[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.8.2.4a
Change from Baseline in MC-QoL by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.4a
Change from Baseline in MC-QoL by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-cou-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.4a
Change from Baseline in MC-QoL by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-cou-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	21	35	44	84	
Mean (StdDev)	49.34 (15.798)	48.65 (11.633)	62.51 (15.995)	63.68 (14.730)	
Median	47.22	49.07	62.96	64.81	
Min, Max	22.2, 78.7	26.9, 75.9	35.2, 97.2	32.4, 98.1	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-ism-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	21	35	44	84	
Mean (StdDev)	43.03 (16.004)	37.81 (14.082)	53.56 (16.310)	49.64 (18.474)	
Median	41.67	32.41	53.70	49.07	
Min, Max	16.7, 79.6	16.7, 68.5	24.0, 92.6	14.8, 90.7	
C2D1 CFB					
n	20	34	43	82	
LS Mean (StdErr) [2]	-5.31 (2.938)	-10.54 (2.032)	-8.79 (2.029)	-13.82 (1.641)	
95% CI [2]	-11.20, 0.59	-14.62, -6.46	-12.81, -4.78	-17.07, -10.58	
Difference (95% CI) in CFB [2]		-5.23 (-11.46, 0.99)		-5.03 (-9.72, -0.34)	
p-value [3]		0.098		0.036	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-ism-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	18	33	45	76	
Mean (StdDev)	43.67 (15.106)	34.15 (15.071)	51.90 (20.470)	45.49 (19.319)	
Median	46.76	33.33	50.00	45.83	
Min, Max	17.6, 71.3	10.2, 69.4	10.2, 88.0	1.9, 93.5	
C3D1 CFB					
n	17	33	44	76	
LS Mean (StdErr) [2]	-4.21 (3.648)	-13.53 (2.416)	-10.20 (2.343)	-17.93 (1.939)	
95% CI [2]	-11.55, 3.13	-18.39, -8.67	-14.84, -5.56	-21.77, -14.09	
Difference (95% CI) in CFB [2]		-9.32 (-17.10, -1.54)		-7.73 (-13.21, -2.25)	
p-value [3]		0.020		0.006	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	17	33	39	80	
Mean (StdDev)	42.92 (18.734)	34.15 (15.412)	53.28 (18.133)	46.00 (21.067)	
Median	37.96	35.19	55.56	46.76	
Min, Max	14.8, 73.1	7.4, 77.8	16.7, 87.0	2.8, 90.7	
C4D1 CFB					
n	16	32	38	79	
LS Mean (StdErr) [2]	-5.51 (3.605)	-14.94 (2.476)	-10.05 (2.747)	-17.97 (2.113)	
95% CI [2]	-12.77, 1.75	-19.93, -9.95	-15.49, -4.61	-22.15, -13.78	
Difference (95% CI) in CFB [2]		-9.43 (-16.89, -1.97)		-7.92 (-14.14, -1.70)	
p-value [3]		0.014		0.013	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	31	41	77	
Mean (StdDev)	41.37 (19.535)	33.00 (14.048)	52.37 (19.585)	43.87 (21.824)	
Median	38.89	33.33	52.78	41.67	
Min, Max	10.2, 75.9	10.2, 71.3	11.1, 88.0	4.6, 93.5	
C5D1 CFB					
n	18	29	41	75	
LS Mean (StdErr) [2]	-3.89 (4.001)	-16.22 (2.812)	-10.68 (2.816)	-20.51 (2.234)	
95% CI [2]	-11.95, 4.17	-21.89, -10.55	-16.26, -5.11	-24.94, -16.09	
Difference (95% CI) in CFB [2]		-12.33 (-20.96, -3.70)		-9.83 (-16.35, -3.31)	
p-value [3]		0.006		0.003	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	19	33	39	78	
Mean (StdDev)	46.00 (16.538)	30.86 (15.001)	52.75 (20.646)	43.28 (23.531)	
Median	45.37	29.63	51.85	43.06	
Min, Max	14.8, 74.1	8.3, 77.8	12.0, 89.8	2.8, 92.6	
C6D1 CFB					
n	18	31	39	76	
LS Mean (StdErr) [2]	-1.85 (3.401)	-18.13 (2.366)	-9.79 (3.122)	-20.83 (2.431)	
95% CI [2]	-8.69, 5.00	-22.89, -13.37	-15.98, -3.61	-25.65, -16.02	
Difference (95% CI) in CFB [2]		-16.28 (-23.51, -9.06)		-11.04 (-18.26, -3.82)	
p-value [3]		<0.0001		0.003	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.8.2.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	18	35	40	76	
Mean (StdDev)	42.13 (18.703)	32.70 (16.922)	50.97 (21.250)	41.95 (24.011)	
Median	42.59	28.70	51.39	40.28	
Min, Max	13.0, 68.5	8.3, 82.4	12.0, 89.8	0.9, 92.6	
C7D1 CFB					
n	17	33	40	74	
LS Mean (StdErr) [2]	-1.91 (3.458)	-13.65 (2.343)	-9.66 (3.183)	-20.27 (2.521)	
95% CI [2]	-8.87, 5.05	-18.36, -8.93	-15.97, -3.35	-25.27, -15.28	
Difference (95% CI) in CFB [2]		-11.74 (-18.98, -4.49)		-10.62 (-17.89, -3.34)	
Hedges'G (95% CI) in CFB		-0.84 (-1.51, -0.26)		-0.50 (-0.90, -0.11)	
p-value [3]		0.002		0.005	
					0.911

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	21	35	44	84	
Mean (StdDev)	53.44 (18.277)	57.70 (13.890)	69.38 (15.291)	71.00 (13.321)	
Median	55.56	58.33	70.83	72.22	
Min, Max	13.9, 91.7	33.3, 86.1	36.1, 100.0	36.1, 97.2	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	21	35	44	84	
Mean (StdDev)	49.07 (18.989)	44.46 (15.195)	58.80 (17.858)	57.24 (18.294)	
Median	50.00	41.67	59.72	55.56	
Min, Max	11.1, 97.2	11.1, 77.8	22.2, 100.0	11.1, 94.4	
C2D1 CFB					
n	20	34	43	82	
LS Mean (StdErr) [2]	-2.31 (3.367)	-12.17 (2.329)	-10.77 (2.335)	-14.05 (1.888)	
95% CI [2]	-9.07, 4.45	-16.85, -7.50	-15.39, -6.15	-17.79, -10.32	
Difference (95% CI) in CFB [2]		-9.86 (-16.99, -2.73)		-3.28 (-8.68, 2.12)	
p-value [3]		0.008		0.231	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	18	33	45	77	
Mean (StdDev)	48.92 (19.436)	41.41 (16.483)	57.59 (21.771)	53.48 (20.366)	
Median	44.44	41.67	58.33	52.78	
Min, Max	22.2, 97.2	13.9, 83.3	11.1, 100.0	5.6, 95.8	
C3D1 CFB					
n	17	33	44	76	
LS Mean (StdErr) [2]	-1.49 (3.964)	-14.83 (2.625)	-11.20 (2.650)	-17.20 (2.193)	
95% CI [2]	-9.47, 6.48	-20.11, -9.55	-16.45, -5.95	-21.54, -12.86	
Difference (95% CI) in CFB [2]		-13.33 (-21.78, -4.88)		-6.00 (-12.20, 0.20)	
p-value [3]		0.003		0.058	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-ism-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	17	33	39	80	
Mean (StdDev)	48.04 (23.256)	42.93 (16.273)	60.11 (21.025)	53.58 (22.078)	
Median	41.67	41.67	63.89	55.56	
Min, Max	11.1, 94.4	13.9, 77.8	11.1, 97.2	8.3, 94.4	
C4D1 CFB					
n	16	32	38	79	
LS Mean (StdErr) [2]	-2.69 (4.011)	-14.01 (2.756)	-11.10 (3.143)	-16.98 (2.417)	
95% CI [2]	-10.77, 5.38	-19.56, -8.46	-17.32, -4.87	-21.77, -12.19	
Difference (95% CI) in CFB [2]		-11.31 (-19.62, -3.01)		-5.88 (-13.00, 1.23)	
p-value [3]		0.009		0.104	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	31	41	77	
Mean (StdDev)	47.22 (21.256)	40.59 (15.090)	60.44 (21.113)	52.15 (22.433)	
Median	47.22	38.89	63.89	52.78	
Min, Max	11.1, 88.9	13.9, 72.2	13.9, 94.4	8.3, 100.0	
C5D1 CFB					
n	18	29	41	75	
LS Mean (StdErr) [2]	-1.78 (4.432)	-16.57 (3.115)	-9.90 (2.983)	-19.50 (2.368)	
95% CI [2]	-10.72, 7.15	-22.85, -10.29	-15.81, -3.99	-24.19, -14.81	
Difference (95% CI) in CFB [2]		-14.79 (-24.35, -5.23)		-9.60 (-16.51, -2.70)	
p-value [3]		0.003		0.007	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-ism-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	19	33	39	78	
Mean (StdDev)	52.34 (18.709)	38.72 (17.221)	58.69 (22.013)	50.00 (24.257)	
Median	47.22	33.33	61.11	50.00	
Min, Max	16.7, 88.9	16.7, 83.3	19.4, 97.2	2.8, 97.2	
C6D1 CFB					
n	18	31	39	76	
LS Mean (StdErr) [2]	2.30 (3.761)	-18.09 (2.616)	-11.07 (3.327)	-20.30 (2.590)	
95% CI [2]	-5.27, 9.87	-23.35, -12.82	-17.67, -4.48	-25.43, -15.16	
Difference (95% CI) in CFB [2]		-20.39 (-28.38, -12.41)		-9.22 (-16.91, -1.53)	
p-value [3]		<0.0001		0.019	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-ism-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	18	35	40	76	
Mean (StdDev)	47.99 (19.521)	40.63 (17.788)	56.74 (21.405)	50.04 (24.472)	
Median	48.61	38.89	55.56	48.61	
Min, Max	13.9, 88.9	13.9, 83.3	13.9, 97.2	0.0, 100.0	
C7D1 CFB					
n	17	33	40	74	
LS Mean (StdErr) [2]	1.82 (3.750)	-13.24 (2.541)	-11.21 (3.343)	-20.11 (2.647)	
95% CI [2]	-5.72, 9.36	-18.35, -8.13	-17.83, -4.58	-25.36, -14.87	
Difference (95% CI) in CFB [2]		-15.06 (-22.92, -7.21)		-8.90 (-16.54, -1.27)	
Hedges'G (95% CI) in CFB		-1.00 (-1.68, -0.41)		-0.40 (-0.80, -0.01)	
p-value [3]		<0.001		0.023	
					0.437

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-ism-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	21	35	44	84	
Mean (StdDev)	50.13 (24.603)	47.38 (17.645)	58.99 (21.584)	61.47 (21.229)	
Median	50.00	47.22	61.11	63.89	
Min, Max	13.9, 94.4	16.7, 80.6	16.7, 97.2	5.6, 100.0	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	21	35	44	84	
Mean (StdDev)	40.48 (23.382)	36.67 (20.565)	51.64 (21.561)	47.95 (24.782)	
Median	33.33	33.33	55.56	44.44	
Min, Max	2.8, 86.1	5.6, 77.8	5.6, 91.7	0.0, 100.0	
C2D1 CFB					
n	20	34	43	82	
LS Mean (StdErr) [2]	-7.27 (3.990)	-10.22 (2.760)	-7.24 (2.535)	-13.09 (2.050)	
95% CI [2]	-15.27, 0.74	-15.76, -4.68	-12.26, -2.22	-17.14, -9.03	
Difference (95% CI) in CFB [2]		-2.95 (-11.40, 5.50)		-5.85 (-11.71, 0.01)	
p-value [3]		0.486		0.050	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	18	33	45	76	
Mean (StdDev)	44.14 (19.708)	31.90 (18.401)	50.25 (24.950)	44.23 (25.279)	
Median	44.44	30.56	47.22	44.44	
Min, Max	8.3, 75.0	2.8, 80.6	5.6, 88.9	0.0, 100.0	
C3D1 CFB					
n	17	33	44	76	
LS Mean (StdErr) [2]	-4.40 (4.944)	-14.14 (3.274)	-8.31 (2.722)	-17.39 (2.252)	
95% CI [2]	-14.35, 5.55	-20.72, -7.55	-13.70, -2.92	-21.85, -12.93	
Difference (95% CI) in CFB [2]		-9.74 (-20.27, 0.80)		-9.09 (-15.45, -2.72)	
p-value [3]		0.069		0.006	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-ism-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	17	33	39	80	
Mean (StdDev)	39.38 (24.121)	33.08 (20.143)	50.64 (22.199)	44.38 (25.862)	
Median	36.11	30.56	50.00	44.44	
Min, Max	8.3, 80.6	0.0, 86.1	13.9, 94.4	0.0, 97.2	
C4D1 CFB					
n	16	32	38	79	
LS Mean (StdErr) [2]	-8.01 (5.416)	-13.90 (3.721)	-8.65 (3.136)	-17.49 (2.411)	
95% CI [2]	-18.92, 2.90	-21.40, -6.41	-14.86, -2.44	-22.27, -12.71	
Difference (95% CI) in CFB [2]		-5.89 (-17.10, 5.32)		-8.84 (-15.94, -1.74)	
p-value [3]		0.295		0.015	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	32	40	77	
Mean (StdDev)	39.18 (24.930)	32.64 (17.483)	49.24 (23.469)	41.61 (27.211)	
Median	38.89	30.56	48.61	41.67	
Min, Max	0.0, 83.3	0.0, 80.6	0.0, 94.4	0.0, 100.0	
C5D1 CFB					
n	18	30	40	75	
LS Mean (StdErr) [2]	-5.31 (5.729)	-15.21 (4.005)	-9.51 (3.353)	-20.83 (2.640)	
95% CI [2]	-16.85, 6.23	-23.27, -7.14	-16.16, -2.87	-26.06, -15.60	
Difference (95% CI) in CFB [2]		-9.90 (-22.15, 2.36)		-11.31 (-19.08, -3.55)	
p-value [3]		0.111		0.005	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	19	33	39	78	
Mean (StdDev)	43.27 (21.741)	29.71 (19.916)	52.78 (23.980)	41.45 (28.458)	
Median	41.67	27.78	52.78	40.28	
Min, Max	0.0, 83.3	2.8, 77.8	8.3, 94.4	0.0, 100.0	
C6D1 CFB					
n	18	31	39	76	
LS Mean (StdErr) [2]	-3.95 (5.011)	-17.85 (3.485)	-6.35 (3.587)	-20.45 (2.793)	
95% CI [2]	-14.04, 6.13	-24.87, -10.84	-13.45, 0.76	-25.98, -14.91	
Difference (95% CI) in CFB [2]		-13.90 (-24.54, -3.26)		-14.10 (-22.39, -5.81)	
p-value [3]		0.012		0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-ism-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	18	35	40	76	
Mean (StdDev)	40.12 (25.834)	30.87 (21.238)	49.72 (25.628)	39.36 (28.546)	
Median	38.89	25.00	47.22	36.11	
Min, Max	2.8, 80.6	0.0, 86.1	0.0, 97.2	0.0, 100.0	
C7D1 CFB					
n	17	33	40	74	
LS Mean (StdErr) [2]	-3.70 (4.865)	-13.92 (3.297)	-6.59 (3.755)	-19.86 (2.974)	
95% CI [2]	-13.49, 6.09	-20.55, -7.28	-14.03, 0.85	-25.75, -13.97	
Difference (95% CI) in CFB [2]		-10.22 (-20.41, -0.02)		-13.27 (-21.85, -4.69)	
Hedges'G (95% CI) in CFB		-0.52 (-1.15, 0.07)		-0.53 (-0.93, -0.14)	
p-value [3]		0.049		0.003	
					0.605

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	21	35	44	84	
Mean (StdDev)	42.26 (19.821)	39.64 (19.211)	54.20 (22.502)	56.35 (22.642)	
Median	45.83	41.67	52.08	54.17	
Min, Max	0.0, 70.8	0.0, 79.2	12.5, 100.0	8.3, 100.0	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	21	35	44	84	
Mean (StdDev)	36.11 (20.469)	31.55 (18.696)	45.83 (22.139)	43.40 (26.187)	
Median	41.67	29.17	45.83	37.50	
Min, Max	0.0, 79.2	0.0, 75.0	4.2, 91.7	0.0, 100.0	
C2D1 CFB					
n	20	34	43	82	
LS Mean (StdErr) [2]	-7.06 (3.804)	-9.17 (2.632)	-7.92 (2.520)	-12.80 (2.038)	
95% CI [2]	-14.70, 0.57	-14.45, -3.88	-12.91, -2.94	-16.84, -8.77	
Difference (95% CI) in CFB [2]		-2.10 (-10.16, 5.96)		-4.88 (-10.71, 0.95)	
p-value [3]		0.603		0.100	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	18	33	45	77	
Mean (StdDev)	36.81 (16.435)	26.89 (18.343)	43.50 (24.517)	38.59 (23.819)	
Median	37.50	25.00	37.50	37.50	
Min, Max	4.2, 66.7	0.0, 62.5	0.0, 91.7	0.0, 95.8	
C3D1 CFB					
n	17	33	44	76	
LS Mean (StdErr) [2]	-5.50 (4.307)	-12.68 (2.852)	-10.71 (2.766)	-18.64 (2.289)	
95% CI [2]	-14.16, 3.17	-18.42, -6.94	-16.19, -5.24	-23.17, -14.10	
Difference (95% CI) in CFB [2]		-7.18 (-16.36, 2.00)		-7.92 (-14.39, -1.45)	
p-value [3]		0.122		0.017	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-ism-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	17	33	39	80	
Mean (StdDev)	39.71 (23.111)	24.75 (18.892)	44.23 (24.005)	39.82 (25.312)	
Median	45.83	25.00	45.83	40.83	
Min, Max	0.0, 75.0	0.0, 79.2	0.0, 91.7	0.0, 95.8	
C4D1 CFB					
n	16	32	38	79	
LS Mean (StdErr) [2]	-5.05 (4.464)	-18.11 (3.067)	-11.27 (3.357)	-18.35 (2.581)	
95% CI [2]	-14.04, 3.94	-24.29, -11.93	-17.91, -4.62	-23.46, -13.24	
Difference (95% CI) in CFB [2]		-13.06 (-22.30, -3.82)		-7.09 (-14.68, 0.51)	
p-value [3]		0.007		0.067	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	32	41	77	
Mean (StdDev)	33.77 (22.860)	22.27 (18.258)	42.99 (24.178)	36.80 (25.519)	
Median	37.50	18.75	45.83	33.33	
Min, Max	0.0, 66.7	0.0, 70.8	0.0, 95.8	0.0, 91.7	
C5D1 CFB					
n	18	30	41	75	
LS Mean (StdErr) [2]	-4.02 (4.307)	-19.84 (3.011)	-13.24 (3.474)	-20.95 (2.757)	
95% CI [2]	-12.69, 4.66	-25.90, -13.77	-20.12, -6.36	-26.42, -15.49	
Difference (95% CI) in CFB [2]		-15.82 (-25.03, -6.60)		-7.71 (-15.76, 0.33)	
p-value [3]		0.001		0.060	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	19	33	39	78	
Mean (StdDev)	41.01 (20.425)	21.46 (17.681)	42.74 (26.417)	36.54 (25.561)	
Median	33.33	20.83	37.50	33.33	
Min, Max	8.3, 75.0	0.0, 79.2	0.0, 100.0	0.0, 95.8	
C6D1 CFB					
n	18	31	39	76	
LS Mean (StdErr) [2]	-2.89 (4.701)	-20.91 (3.269)	-11.86 (3.604)	-22.09 (2.806)	
95% CI [2]	-12.35, 6.57	-27.49, -14.33	-19.00, -4.72	-27.65, -16.54	
Difference (95% CI) in CFB [2]		-18.02 (-28.00, -8.04)		-10.23 (-18.56, -1.91)	
p-value [3]		<0.001		0.016	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	18	35	40	76	
Mean (StdDev)	34.72 (21.721)	23.21 (20.294)	41.67 (26.987)	35.58 (28.173)	
Median	33.33	16.67	35.42	31.25	
Min, Max	0.0, 70.8	0.0, 79.2	0.0, 100.0	0.0, 95.8	
C7D1 CFB					
n	17	33	40	74	
LS Mean (StdErr) [2]	-2.58 (4.137)	-14.73 (2.803)	-11.39 (3.831)	-20.04 (3.034)	
95% CI [2]	-10.90, 5.75	-20.37, -9.09	-18.98, -3.80	-26.05, -14.03	
Difference (95% CI) in CFB [2]		-12.15 (-20.82, -3.49)		-8.65 (-17.40, 0.10)	
Hedges'G (95% CI) in CFB		-0.73 (-1.38, -0.14)		-0.34 (-0.74, 0.05)	
p-value [3]		0.007		0.053	
					0.639

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	21	35	44	84	
Mean (StdDev)	48.81 (22.713)	43.33 (16.642)	69.70 (19.028)	63.00 (21.465)	
Median	50.00	41.67	75.00	58.33	
Min, Max	0.0, 83.3	16.7, 75.0	8.3, 100.0	8.3, 100.0	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	21	35	44	84	
Mean (StdDev)	46.43 (18.366)	34.05 (16.834)	59.09 (20.634)	44.35 (18.529)	
Median	41.67	33.33	58.33	41.67	
Min, Max	0.0, 83.3	0.0, 66.7	0.0, 91.7	0.0, 83.3	
C2D1 CFB					
n	20	34	43	82	
LS Mean (StdErr) [2]	-4.62 (3.824)	-9.01 (2.645)	-9.73 (3.605)	-17.29 (2.915)	
95% CI [2]	-12.30, 3.06	-14.32, -3.70	-16.86, -2.59	-23.06, -11.51	
Difference (95% CI) in CFB [2]		-4.39 (-12.49, 3.72)		-7.56 (-15.90, 0.78)	
p-value [3]		0.282		0.075	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.8.2.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	18	33	45	77	
Mean (StdDev)	40.28 (20.858)	33.59 (16.203)	56.48 (21.752)	41.77 (20.613)	
Median	41.67	33.33	58.33	41.67	
Min, Max	0.0, 66.7	0.0, 66.7	0.0, 100.0	0.0, 91.7	
C3D1 CFB					
n	17	33	44	76	
LS Mean (StdErr) [2]	-9.24 (5.760)	-9.56 (3.815)	-12.42 (3.813)	-20.27 (3.155)	
95% CI [2]	-20.83, 2.35	-17.23, -1.88	-19.97, -4.87	-26.52, -14.03	
Difference (95% CI) in CFB [2]		-0.32 (-12.60, 11.96)		-7.86 (-16.78, 1.06)	
p-value [3]		0.959		0.084	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.8.2.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	17	33	39	80	
Mean (StdDev)	44.61 (23.188)	29.80 (13.181)	58.76 (21.794)	40.42 (22.623)	
Median	41.67	25.00	58.33	33.33	
Min, Max	0.0, 75.0	0.0, 50.0	16.7, 100.0	0.0, 100.0	
C4D1 CFB					
n	16	32	38	79	
LS Mean (StdErr) [2]	-7.37 (5.398)	-14.49 (3.709)	-9.25 (4.259)	-21.54 (3.275)	
95% CI [2]	-18.25, 3.50	-21.96, -7.02	-17.69, -0.82	-28.03, -15.05	
Difference (95% CI) in CFB [2]		-7.11 (-18.29, 4.06)		-12.29 (-21.93, -2.65)	
p-value [3]		0.206		0.013	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-ism-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	31	41	77	
Mean (StdDev)	45.61 (25.665)	30.38 (15.146)	57.11 (25.520)	39.94 (21.559)	
Median	50.00	33.33	58.33	33.33	
Min, Max	0.0, 91.7	0.0, 66.7	8.3, 100.0	8.3, 100.0	
C5D1 CFB					
n	18	29	41	75	
LS Mean (StdErr) [2]	-4.60 (5.658)	-12.48 (3.977)	-11.28 (4.029)	-21.76 (3.197)	
95% CI [2]	-16.00, 6.80	-20.50, -4.47	-19.26, -3.30	-28.10, -15.43	
Difference (95% CI) in CFB [2]		-7.89 (-20.09, 4.32)		-10.48 (-19.81, -1.15)	
p-value [3]		0.200		0.028	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-ism-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	19	33	39	78	
Mean (StdDev)	45.18 (23.293)	29.55 (16.150)	54.91 (25.270)	42.09 (24.504)	
Median	41.67	33.33	58.33	33.33	
Min, Max	0.0, 100.0	0.0, 75.0	0.0, 100.0	0.0, 91.7	
C6D1 CFB					
n	18	31	39	76	
LS Mean (StdErr) [2]	-5.88 (5.176)	-13.50 (3.600)	-12.76 (4.358)	-20.99 (3.393)	
95% CI [2]	-16.30, 4.54	-20.75, -6.25	-21.39, -4.12	-27.71, -14.27	
Difference (95% CI) in CFB [2]		-7.62 (-18.61, 3.37)		-8.23 (-18.30, 1.84)	
p-value [3]		0.170		0.108	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-ism-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	18	35	40	76	
Mean (StdDev)	45.37 (20.457)	33.33 (16.789)	56.04 (24.749)	38.16 (22.903)	
Median	45.83	25.00	58.33	33.33	
Min, Max	0.0, 75.0	8.3, 83.3	0.0, 100.0	0.0, 91.7	
C7D1 CFB					
n	17	33	40	74	
LS Mean (StdErr) [2]	-6.39 (5.107)	-11.89 (3.461)	-11.31 (4.279)	-22.37 (3.389)	
95% CI [2]	-16.66, 3.89	-18.85, -4.93	-19.79, -2.84	-29.08, -15.65	
Difference (95% CI) in CFB [2]		-5.51 (-16.21, 5.19)		-11.05 (-20.83, -1.28)	
Hedges'G (95% CI) in CFB		-0.27 (-0.88, 0.32)		-0.39 (-0.79, -0.00)	
p-value [3]		0.306		0.027	
					0.670

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-ism-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	12	25	53	94	
Mean (StdDev)	58.80 (16.228)	60.44 (14.831)	58.13 (17.297)	58.94 (15.681)	
Median	55.09	61.11	60.19	58.33	
Min, Max	36.1, 95.4	30.6, 98.1	22.2, 97.2	26.9, 91.7	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-tryp-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	52	94	
Mean (StdDev)	48.93 (13.991)	49.16 (19.018)	50.46 (17.580)	45.36 (17.827)	
Median	48.15	49.07	52.78	44.44	
Min, Max	27.8, 75.0	17.6, 90.7	16.7, 92.6	14.8, 88.9	
C2D1 CFB					
n	12	24	51	92	
LS Mean (StdErr) [2]	-8.21 (4.670)	-10.74 (2.957)	-7.49 (1.624)	-13.15 (1.284)	
95% CI [2]	-17.71, 1.30	-16.76, -4.72	-10.70, -4.28	-15.69, -10.61	
Difference (95% CI) in CFB [2]		-2.54 (-13.18, 8.11)		-5.66 (-9.63, -1.69)	
p-value [3]		0.631		0.006	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-tryp-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	24	50	85	
Mean (StdDev)	47.29 (22.374)	47.22 (17.894)	50.13 (18.678)	40.60 (18.910)	
Median	46.30	45.37	49.54	37.96	
Min, Max	10.2, 88.0	15.7, 93.5	16.7, 88.0	1.9, 88.0	
C3D1 CFB					
n	12	24	49	85	
LS Mean (StdErr) [2]	-9.59 (4.405)	-12.99 (2.789)	-8.24 (2.075)	-17.52 (1.642)	
95% CI [2]	-18.56, -0.63	-18.67, -7.32	-12.35, -4.14	-20.77, -14.27	
Difference (95% CI) in CFB [2]		-3.40 (-13.44, 6.64)		-9.28 (-14.31, -4.25)	
p-value [3]		0.496		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-tryp-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	11	22	45	91	
Mean (StdDev)	45.03 (17.472)	49.03 (17.823)	51.38 (19.052)	40.97 (20.581)	
Median	43.52	47.22	55.56	39.81	
Min, Max	20.4, 72.2	26.9, 90.7	14.8, 87.0	2.8, 88.0	
C4D1 CFB					
n	10	22	44	89	
LS Mean (StdErr) [2]	-11.58 (5.276)	-13.55 (3.337)	-8.36 (2.274)	-18.12 (1.684)	
95% CI [2]	-22.37, -0.79	-20.38, -6.73	-12.86, -3.86	-21.45, -14.79	
Difference (95% CI) in CFB [2]		-1.98 (-13.80, 9.84)		-9.76 (-15.17, -4.36)	
p-value [3]		0.735		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-tryp-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	25	48	83	
Mean (StdDev)	42.82 (15.479)	44.56 (19.197)	50.41 (20.933)	39.60 (20.780)	
Median	38.89	35.19	52.31	37.04	
Min, Max	18.5, 69.4	13.9, 86.1	10.2, 88.0	4.6, 93.5	
C5D1 CFB					
n	11	24	48	80	
LS Mean (StdErr) [2]	-13.51 (4.844)	-14.91 (3.032)	-7.47 (2.413)	-20.17 (1.984)	
95% CI [2]	-23.38, -3.65	-21.09, -8.74	-12.25, -2.70	-24.09, -16.24	
Difference (95% CI) in CFB [2]		-1.40 (-12.24, 9.44)		-12.69 (-18.65, -6.74)	
p-value [3]		0.794		<0.0001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-tryp-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	25	46	86	
Mean (StdDev)	41.28 (15.641)	44.04 (21.353)	52.96 (19.840)	38.30 (22.184)	
Median	39.35	41.67	52.31	34.26	
Min, Max	18.5, 64.8	11.1, 89.8	12.0, 89.8	2.8, 92.6	
C6D1 CFB					
n	11	24	46	83	
LS Mean (StdErr) [2]	-15.77 (5.775)	-16.05 (3.615)	-5.00 (2.468)	-20.53 (1.943)	
95% CI [2]	-27.53, -4.00	-23.41, -8.69	-9.88, -0.11	-24.37, -16.68	
Difference (95% CI) in CFB [2]		-0.29 (-13.20, 12.63)		-15.53 (-21.56, -9.50)	
p-value [3]		0.964		<0.0001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-tryp-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	11	24	47	87	
Mean (StdDev)	42.34 (17.362)	46.03 (22.343)	49.61 (21.389)	37.10 (22.111)	
Median	38.89	41.67	52.78	30.56	
Min, Max	16.7, 71.3	13.9, 89.8	12.0, 89.8	0.9, 92.6	
C7D1 CFB					
n	10	23	47	84	
LS Mean (StdErr) [2]	-8.14 (6.687)	-12.14 (4.093)	-8.12 (2.437)	-20.56 (1.891)	
95% CI [2]	-21.80, 5.51	-20.50, -3.78	-12.94, -3.29	-24.31, -16.82	
Difference (95% CI) in CFB [2]		-4.00 (-19.06, 11.07)		-12.45 (-18.35, -6.54)	
Hedges'G (95% CI) in CFB		-0.19 (-0.98, 0.57)		-0.72 (-1.11, -0.36)	
p-value [3]		0.592		<0.0001	
					0.221

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-tryp-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	12	25	53	94	
Mean (StdDev)	65.28 (19.007)	66.44 (14.071)	63.99 (17.736)	67.26 (14.989)	
Median	63.89	69.44	63.89	69.44	
Min, Max	38.9, 97.2	41.7, 97.2	13.9, 100.0	33.3, 94.4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-tryp-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	52	94	
Mean (StdDev)	54.70 (19.291)	54.57 (19.643)	55.90 (18.676)	53.19 (18.071)	
Median	50.00	55.56	55.56	54.17	
Min, Max	22.2, 88.9	11.1, 88.9	11.1, 100.0	11.1, 94.4	
C2D1 CFB					
n	12	24	51	92	
LS Mean (StdErr) [2]	-9.31 (5.579)	-11.20 (3.533)	-7.96 (1.853)	-13.93 (1.465)	
95% CI [2]	-20.66, 2.04	-18.39, -4.01	-11.62, -4.30	-16.82, -11.03	
Difference (95% CI) in CFB [2]		-1.89 (-14.62, 10.83)		-5.96 (-10.49, -1.43)	
p-value [3]		0.764		0.010	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	24	50	86	
Mean (StdDev)	54.70 (27.531)	54.40 (20.834)	55.22 (19.767)	48.59 (19.693)	
Median	50.00	54.17	56.94	44.44	
Min, Max	11.1, 100.0	16.7, 91.7	16.7, 97.2	5.6, 95.8	
C3D1 CFB					
n	12	24	49	85	
LS Mean (StdErr) [2]	-9.16 (5.768)	-11.45 (3.652)	-9.68 (2.242)	-19.02 (1.775)	
95% CI [2]	-20.90, 2.57	-18.88, -4.02	-14.11, -5.24	-22.54, -15.51	
Difference (95% CI) in CFB [2]		-2.29 (-15.44, 10.86)		-9.35 (-14.78, -3.91)	
p-value [3]		0.726		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	11	22	45	91	
Mean (StdDev)	55.30 (26.366)	55.93 (19.685)	56.73 (21.431)	49.15 (21.259)	
Median	55.56	58.33	61.11	47.22	
Min, Max	19.4, 97.2	27.8, 94.4	11.1, 94.4	8.3, 91.7	
C4D1 CFB					
n	10	22	44	89	
LS Mean (StdErr) [2]	-9.57 (6.448)	-11.55 (4.078)	-9.41 (2.559)	-18.05 (1.895)	
95% CI [2]	-22.76, 3.62	-19.89, -3.21	-14.47, -4.35	-21.80, -14.31	
Difference (95% CI) in CFB [2]		-1.98 (-16.42, 12.47)		-8.65 (-14.73, -2.57)	
p-value [3]		0.782		0.006	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	25	48	83	
Mean (StdDev)	53.01 (22.951)	50.67 (20.147)	57.07 (21.773)	48.28 (21.578)	
Median	51.39	50.00	59.72	50.00	
Min, Max	19.4, 94.4	8.3, 88.9	11.1, 91.7	8.3, 100.0	
C5D1 CFB					
n	11	24	48	80	
LS Mean (StdErr) [2]	-10.23 (5.746)	-14.51 (3.597)	-7.34 (2.544)	-20.01 (2.092)	
95% CI [2]	-21.94, 1.47	-21.84, -7.18	-12.38, -2.31	-24.15, -15.87	
Difference (95% CI) in CFB [2]		-4.27 (-17.13, 8.58)		-12.66 (-18.94, -6.38)	
p-value [3]		0.503		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	25	46	86	
Mean (StdDev)	48.84 (22.674)	51.44 (24.151)	58.64 (20.364)	45.25 (22.494)	
Median	41.67	55.56	61.11	41.67	
Min, Max	22.2, 97.2	2.8, 94.4	16.7, 94.4	2.8, 97.2	
C6D1 CFB					
n	11	24	46	83	
LS Mean (StdErr) [2]	-14.29 (6.750)	-14.33 (4.225)	-5.65 (2.606)	-21.14 (2.052)	
95% CI [2]	-28.04, -0.54	-22.94, -5.73	-10.81, -0.49	-25.20, -17.07	
Difference (95% CI) in CFB [2]		-0.05 (-15.15, 15.05)		-15.49 (-21.86, -9.12)	
p-value [3]		0.995		<0.0001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	11	24	47	87	
Mean (StdDev)	49.24 (23.044)	52.78 (23.008)	55.14 (20.682)	45.50 (22.777)	
Median	47.22	54.17	55.56	41.67	
Min, Max	19.4, 97.2	13.9, 94.4	13.9, 88.9	0.0, 100.0	
C7D1 CFB					
n	10	23	47	84	
LS Mean (StdErr) [2]	-7.10 (7.258)	-11.05 (4.442)	-8.60 (2.560)	-20.75 (1.987)	
95% CI [2]	-21.92, 7.72	-20.12, -1.98	-13.66, -3.53	-24.68, -16.82	
Difference (95% CI) in CFB [2]		-3.95 (-20.30, 12.40)		-12.16 (-18.36, -5.95)	
Hedges'G (95% CI) in CFB		-0.18 (-0.96, 0.58)		-0.67 (-1.05, -0.31)	
p-value [3]		0.625		<0.001	
					0.215

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	12	25	53	94	
Mean (StdDev)	58.33 (20.854)	58.11 (19.949)	55.63 (23.369)	57.12 (21.584)	
Median	59.72	61.11	55.56	58.33	
Min, Max	16.7, 97.2	19.4, 100.0	13.9, 94.4	5.6, 100.0	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	52	94	
Mean (StdDev)	48.93 (19.855)	48.56 (20.820)	47.81 (23.411)	43.59 (24.889)	
Median	50.00	50.00	50.00	40.28	
Min, Max	25.0, 83.3	11.1, 100.0	2.8, 91.7	0.0, 100.0	
C2D1 CFB					
n	12	24	51	92	
LS Mean (StdErr) [2]	-6.42 (5.035)	-9.24 (3.189)	-8.42 (2.177)	-13.90 (1.722)	
95% CI [2]	-16.67, 3.82	-15.73, -2.75	-12.72, -4.12	-17.31, -10.50	
Difference (95% CI) in CFB [2]		-2.82 (-14.30, 8.66)		-5.48 (-10.80, -0.16)	
p-value [3]		0.621		0.044	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	24	50	85	
Mean (StdDev)	48.08 (24.984)	45.72 (19.659)	48.61 (23.465)	39.02 (25.007)	
Median	41.67	47.22	47.22	33.33	
Min, Max	8.3, 86.1	13.9, 100.0	5.6, 88.9	0.0, 97.2	
C3D1 CFB					
n	12	24	49	85	
LS Mean (StdErr) [2]	-7.34 (4.966)	-12.85 (3.145)	-7.84 (2.548)	-17.98 (2.017)	
95% CI [2]	-17.45, 2.76	-19.25, -6.45	-12.88, -2.80	-21.97, -13.99	
Difference (95% CI) in CFB [2]		-5.51 (-16.83, 5.82)		-10.14 (-16.32, -3.97)	
p-value [3]		0.330		0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	11	22	45	91	
Mean (StdDev)	43.18 (19.459)	49.75 (21.136)	48.21 (24.087)	38.98 (25.247)	
Median	38.89	50.00	47.22	36.11	
Min, Max	19.4, 69.4	11.1, 97.2	8.3, 94.4	0.0, 97.2	
C4D1 CFB					
n	10	22	44	89	
LS Mean (StdErr) [2]	-9.24 (6.975)	-11.27 (4.411)	-10.00 (2.713)	-19.32 (2.009)	
95% CI [2]	-23.51, 5.02	-20.29, -2.25	-15.37, -4.63	-23.30, -15.35	
Difference (95% CI) in CFB [2]		-2.03 (-17.66, 13.60)		-9.32 (-15.77, -2.87)	
p-value [3]		0.792		0.005	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	25	47	84	
Mean (StdDev)	41.20 (20.165)	44.67 (22.076)	47.22 (25.174)	37.29 (25.701)	
Median	40.28	44.44	47.22	36.11	
Min, Max	11.1, 77.8	2.8, 97.2	0.0, 94.4	0.0, 100.0	
C5D1 CFB					
n	11	24	47	81	
LS Mean (StdErr) [2]	-13.19 (5.909)	-12.51 (3.698)	-8.18 (3.013)	-21.85 (2.429)	
95% CI [2]	-25.22, -1.15	-20.04, -4.98	-14.14, -2.21	-26.66, -17.04	
Difference (95% CI) in CFB [2]		0.68 (-12.54, 13.90)		-13.67 (-21.08, -6.27)	
p-value [3]		0.917		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-tryp-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	25	46	86	
Mean (StdDev)	40.97 (19.789)	43.11 (23.558)	51.93 (24.066)	36.47 (27.455)	
Median	40.28	44.44	50.00	30.56	
Min, Max	11.1, 66.7	0.0, 97.2	0.0, 94.4	0.0, 100.0	
C6D1 CFB					
n	11	24	46	83	
LS Mean (StdErr) [2]	-14.01 (6.580)	-14.40 (4.118)	-4.44 (3.000)	-21.76 (2.362)	
95% CI [2]	-27.41, -0.61	-22.79, -6.01	-10.38, 1.49	-26.44, -17.09	
Difference (95% CI) in CFB [2]		-0.39 (-15.11, 14.33)		-17.32 (-24.65, -9.99)	
p-value [3]		0.957		<0.0001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-tryp-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	11	24	47	87	
Mean (StdDev)	42.93 (22.613)	45.49 (26.197)	47.64 (26.700)	34.26 (26.419)	
Median	38.89	44.44	47.22	30.56	
Min, Max	13.9, 80.6	5.6, 100.0	0.0, 97.2	0.0, 100.0	
C7D1 CFB					
n	10	23	47	84	
LS Mean (StdErr) [2]	-5.46 (7.923)	-10.61 (4.850)	-8.26 (2.989)	-22.21 (2.320)	
95% CI [2]	-21.64, 10.72	-20.51, -0.70	-14.18, -2.35	-26.80, -17.62	
Difference (95% CI) in CFB [2]		-5.15 (-23.00, 12.70)		-13.95 (-21.19, -6.71)	
Hedges'G (95% CI) in CFB		-0.21 (-1.00, 0.55)		-0.66 (-1.04, -0.30)	
p-value [3]		0.560		<0.001	
					0.263

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	12	25	53	94	
Mean (StdDev)	48.61 (21.565)	55.33 (23.647)	50.74 (22.574)	50.40 (22.740)	
Median	50.00	58.33	50.00	47.92	
Min, Max	12.5, 100.0	0.0, 100.0	0.0, 100.0	8.3, 100.0	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	52	94	
Mean (StdDev)	37.82 (14.279)	44.67 (26.174)	43.91 (23.418)	38.65 (24.345)	
Median	41.67	45.83	43.75	33.33	
Min, Max	12.5, 58.3	0.0, 100.0	0.0, 91.7	0.0, 100.0	
C2D1 CFB					
n	12	24	51	92	
LS Mean (StdErr) [2]	-11.60 (5.213)	-10.56 (3.301)	-5.52 (2.108)	-10.72 (1.667)	
95% CI [2]	-22.20, -0.99	-17.28, -3.85	-9.69, -1.35	-14.02, -7.42	
Difference (95% CI) in CFB [2]		1.04 (-10.85, 12.92)		-5.20 (-10.35, -0.05)	
p-value [3]		0.860		0.048	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-tryp-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	24	50	86	
Mean (StdDev)	35.90 (23.108)	39.41 (22.622)	43.07 (22.441)	33.88 (22.932)	
Median	37.50	37.50	41.67	33.33	
Min, Max	0.0, 79.2	0.0, 95.8	0.0, 91.7	0.0, 95.8	
C3D1 CFB					
n	12	24	49	85	
LS Mean (StdErr) [2]	-11.72 (5.167)	-15.01 (3.272)	-6.84 (2.456)	-15.59 (1.943)	
95% CI [2]	-22.24, -1.21	-21.67, -8.35	-11.69, -1.98	-19.44, -11.75	
Difference (95% CI) in CFB [2]		-3.29 (-15.07, 8.50)		-8.75 (-14.71, -2.80)	
p-value [3]		0.574		0.004	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	11	22	45	91	
Mean (StdDev)	30.30 (15.376)	40.53 (19.720)	45.93 (24.385)	34.18 (25.488)	
Median	25.00	41.67	45.83	29.17	
Min, Max	4.2, 54.2	0.0, 83.3	0.0, 91.7	0.0, 95.8	
C4D1 CFB					
n	10	22	44	89	
LS Mean (StdErr) [2]	-18.44 (4.633)	-18.04 (2.930)	-5.51 (2.933)	-16.34 (2.172)	
95% CI [2]	-27.92, -8.97	-24.03, -12.05	-11.31, 0.30	-20.64, -12.04	
Difference (95% CI) in CFB [2]		0.40 (-9.98, 10.78)		-10.83 (-17.80, -3.86)	
p-value [3]		0.938		0.003	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	25	48	84	
Mean (StdDev)	29.17 (12.688)	37.00 (23.426)	42.80 (25.407)	31.20 (24.735)	
Median	27.08	33.33	47.92	25.00	
Min, Max	4.2, 50.0	0.0, 87.5	0.0, 95.8	0.0, 91.7	
C5D1 CFB					
n	11	24	48	81	
LS Mean (StdErr) [2]	-18.77 (5.820)	-18.20 (3.643)	-7.69 (2.915)	-20.19 (2.369)	
95% CI [2]	-30.62, -6.92	-25.62, -10.78	-13.45, -1.92	-24.88, -15.50	
Difference (95% CI) in CFB [2]		0.57 (-12.45, 13.59)		-12.50 (-19.67, -5.33)	
p-value [3]		0.929		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-tryp-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	25	46	86	
Mean (StdDev)	28.82 (15.837)	35.33 (23.696)	45.65 (25.214)	31.10 (24.677)	
Median	31.25	33.33	54.17	29.17	
Min, Max	0.0, 58.3	0.0, 91.7	0.0, 100.0	0.0, 95.8	
C6D1 CFB					
n	11	24	46	83	
LS Mean (StdErr) [2]	-21.05 (6.921)	-21.04 (4.332)	-3.81 (2.948)	-19.33 (2.322)	
95% CI [2]	-35.14, -6.95	-29.86, -12.21	-9.64, 2.03	-23.93, -14.74	
Difference (95% CI) in CFB [2]		0.01 (-15.47, 15.49)		-15.53 (-22.73, -8.32)	
p-value [3]		0.999		<0.0001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	11	24	47	87	
Mean (StdDev)	28.03 (19.011)	38.72 (25.314)	42.20 (26.218)	29.74 (26.620)	
Median	29.17	41.67	37.50	20.83	
Min, Max	0.0, 58.3	0.0, 95.8	0.0, 100.0	0.0, 95.8	
C7D1 CFB					
n	10	23	47	84	
LS Mean (StdErr) [2]	-12.57 (6.719)	-13.70 (4.113)	-7.90 (3.066)	-19.42 (2.380)	
95% CI [2]	-26.29, 1.16	-22.10, -5.30	-13.97, -1.83	-24.12, -14.71	
Difference (95% CI) in CFB [2]		-1.14 (-16.27, 14.00)		-11.52 (-18.94, -4.09)	
Hedges'G (95% CI) in CFB		-0.05 (-0.83, 0.71)		-0.53 (-0.91, -0.17)	
p-value [3]		0.879		0.003	
					0.247

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	12	25	53	94	
Mean (StdDev)	61.11 (15.215)	59.67 (18.270)	63.36 (23.815)	56.56 (22.956)	
Median	58.33	58.33	66.67	58.33	
Min, Max	33.3, 83.3	16.7, 91.7	0.0, 100.0	8.3, 100.0	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	52	94	
Mean (StdDev)	53.85 (19.725)	44.00 (22.116)	55.29 (21.071)	40.60 (17.592)	
Median	58.33	41.67	50.00	37.50	
Min, Max	16.7, 91.7	0.0, 83.3	0.0, 91.7	0.0, 83.3	
C2D1 CFB					
n	12	24	51	92	
LS Mean (StdErr) [2]	-3.21 (7.991)	-13.88 (5.060)	-7.66 (2.711)	-13.38 (2.144)	
95% CI [2]	-19.47, 13.05	-24.17, -3.59	-13.01, -2.30	-17.61, -9.14	
Difference (95% CI) in CFB [2]		-10.67 (-28.89, 7.55)		-5.72 (-12.35, 0.91)	
p-value [3]		0.242		0.090	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	24	50	86	
Mean (StdDev)	45.51 (16.879)	45.83 (19.505)	53.50 (23.696)	37.50 (19.460)	
Median	41.67	45.83	58.33	33.33	
Min, Max	16.7, 75.0	16.7, 75.0	0.0, 100.0	0.0, 91.7	
C3D1 CFB					
n	12	24	49	85	
LS Mean (StdErr) [2]	-13.38 (7.135)	-14.01 (4.518)	-8.50 (3.368)	-15.49 (2.666)	
95% CI [2]	-27.89, 1.14	-23.21, -4.82	-15.16, -1.84	-20.77, -10.22	
Difference (95% CI) in CFB [2]		-0.64 (-16.91, 15.63)		-6.99 (-15.15, 1.17)	
p-value [3]		0.937		0.093	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-tryp-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	11	22	45	91	
Mean (StdDev)	49.24 (20.226)	43.18 (23.093)	55.74 (23.625)	35.90 (20.134)	
Median	41.67	33.33	58.33	33.33	
Min, Max	16.7, 75.0	16.7, 91.7	0.0, 100.0	0.0, 100.0	
C4D1 CFB					
n	10	22	44	89	
LS Mean (StdErr) [2]	-10.87 (8.028)	-17.44 (5.077)	-6.52 (3.534)	-18.27 (2.617)	
95% CI [2]	-27.29, 5.55	-27.83, -7.06	-13.51, 0.47	-23.44, -13.09	
Difference (95% CI) in CFB [2]		-6.57 (-24.56, 11.42)		-11.75 (-20.15, -3.35)	
p-value [3]		0.461		0.006	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-tryp-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	25	48	83	
Mean (StdDev)	44.44 (18.914)	41.00 (20.822)	55.73 (27.080)	36.04 (20.167)	
Median	45.83	33.33	58.33	33.33	
Min, Max	8.3, 66.7	0.0, 83.3	0.0, 100.0	8.3, 100.0	
C5D1 CFB					
n	11	24	48	80	
LS Mean (StdErr) [2]	-13.81 (7.878)	-16.78 (4.931)	-5.32 (3.373)	-16.68 (2.773)	
95% CI [2]	-29.86, 2.23	-26.82, -6.73	-11.99, 1.36	-22.17, -11.19	
Difference (95% CI) in CFB [2]		-2.96 (-20.59, 14.66)		-11.36 (-19.69, -3.04)	
p-value [3]		0.734		0.008	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-tryp-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	25	46	86	
Mean (StdDev)	44.44 (18.577)	42.00 (24.114)	53.62 (26.096)	37.31 (22.713)	
Median	45.83	33.33	58.33	33.33	
Min, Max	8.3, 66.7	0.0, 91.7	0.0, 100.0	0.0, 91.7	
C6D1 CFB					
n	11	24	46	83	
LS Mean (StdErr) [2]	-14.91 (8.272)	-16.18 (5.178)	-7.61 (3.525)	-17.29 (2.776)	
95% CI [2]	-31.76, 1.94	-26.73, -5.63	-14.59, -0.64	-22.79, -11.80	
Difference (95% CI) in CFB [2]		-1.27 (-19.78, 17.23)		-9.68 (-18.29, -1.07)	
p-value [3]		0.889		0.028	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-tryp-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	11	24	47	87	
Mean (StdDev)	48.48 (17.802)	42.01 (23.245)	53.72 (25.109)	35.15 (20.508)	
Median	50.00	37.50	58.33	33.33	
Min, Max	8.3, 75.0	8.3, 91.7	0.0, 100.0	0.0, 91.7	
C7D1 CFB					
n	10	23	47	84	
LS Mean (StdErr) [2]	-10.48 (9.026)	-16.89 (5.525)	-7.18 (3.357)	-17.28 (2.606)	
95% CI [2]	-28.91, 7.95	-28.18, -5.61	-13.82, -0.54	-22.43, -12.12	
Difference (95% CI) in CFB [2]		-6.41 (-26.75, 13.92)		-10.09 (-18.23, -1.96)	
Hedges'G (95% CI) in CFB		-0.23 (-1.02, 0.53)		-0.43 (-0.80, -0.07)	
p-value [3]		0.524		0.015	
					0.943

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-tryp-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.7a
Change from Baseline in MC-QoL by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	61	110	4	9	
Mean (StdDev)	57.48 (17.218)	58.69 (15.476)	70.14 (4.863)	66.26 (14.180)	
Median	56.48	58.33	72.22	63.89	
Min, Max	22.2, 97.2	26.9, 98.1	63.0, 73.1	46.3, 87.0	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.7a
Change from Baseline in MC-QoL by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	61	111	4	8	
Mean (StdDev)	49.32 (16.841)	45.63 (18.045)	62.96 (11.809)	53.47 (17.912)	
Median	50.00	44.44	59.26	50.46	
Min, Max	16.7, 92.6	14.8, 90.7	53.7, 79.6	25.9, 84.3	
C2D1 CFB					
n	59	108	4	8	
LS Mean (StdErr) [2]	-6.94 (1.745)	-12.23 (1.389)	-13.14 (9.407)	-14.91 (7.417)	
95% CI [2]	-10.38, -3.49	-14.98, -9.49	-34.83, 8.55	-32.01, 2.19	
Difference (95% CI) in CFB [2]		-5.30 (-9.12, -1.47)		-1.77 (-20.64, 17.10)	
p-value [3]		0.007		0.834	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-ecog-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.7a
Change from Baseline in MC-QoL by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	59	101	4	8	
Mean (StdDev)	48.90 (19.633)	41.40 (18.594)	59.03 (12.176)	50.35 (20.892)	
Median	49.07	37.96	58.80	49.07	
Min, Max	10.2, 88.0	1.9, 93.5	47.2, 71.3	25.9, 80.6	
C3D1 CFB					
n	57	101	4	8	
LS Mean (StdErr) [2]	-7.30 (2.075)	-15.90 (1.630)	-10.65 (11.606)	-15.28 (9.151)	
95% CI [2]	-11.40, -3.20	-19.12, -12.69	-37.41, 16.12	-36.38, 5.82	
Difference (95% CI) in CFB [2]		-8.60 (-13.15, -4.06)		-4.63 (-27.91, 18.65)	
p-value [3]		<0.001		0.659	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-ecog-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.7a
Change from Baseline in MC-QoL by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	52	104	4	9	
Mean (StdDev)	48.77 (18.735)	41.37 (19.770)	67.82 (6.607)	56.07 (22.068)	
Median	45.37	38.89	69.91	62.04	
Min, Max	14.8, 87.0	2.8, 90.7	58.3, 73.1	18.5, 81.5	
C4D1 CFB					
n	50	102	4	9	
LS Mean (StdErr) [2]	-8.33 (2.317)	-16.85 (1.771)	-2.11 (12.919)	-10.72 (10.237)	
95% CI [2]	-12.91, -3.75	-20.35, -13.35	-31.33, 27.12	-33.88, 12.44	
Difference (95% CI) in CFB [2]		-8.52 (-13.48, -3.56)		-8.61 (-33.82, 16.60)	
p-value [3]		<0.001		0.460	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-ecog-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.7a
Change from Baseline in MC-QoL by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	56	99	4	9	
Mean (StdDev)	47.85 (20.299)	39.53 (19.727)	63.43 (8.469)	54.12 (24.577)	
Median	47.29	35.19	63.89	63.89	
Min, Max	10.2, 88.0	4.6, 93.5	52.8, 73.1	20.4, 84.3	
C5D1 CFB					
n	55	95	4	9	
LS Mean (StdErr) [2]	-7.76 (2.415)	-18.79 (1.923)	-8.61 (13.306)	-15.65 (10.543)	
95% CI [2]	-12.54, -2.99	-22.59, -14.99	-38.71, 21.49	-39.50, 8.20	
Difference (95% CI) in CFB [2]		-11.03 (-16.35, -5.71)		-7.04 (-33.00, 18.93)	
p-value [3]		<0.0001		0.555	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.7a
Change from Baseline in MC-QoL by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	102	4	9	
Mean (StdDev)	49.35 (19.605)	38.24 (21.588)	66.67 (8.453)	54.84 (22.537)	
Median	48.61	35.65	68.98	62.04	
Min, Max	12.0, 89.8	2.8, 92.6	54.6, 74.1	21.3, 82.4	
C6D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-6.39 (2.552)	-19.73 (1.993)	3.24 (12.377)	-7.87 (9.808)	
95% CI [2]	-11.44, -1.35	-23.67, -15.79	-24.76, 31.24	-30.06, 14.32	
Difference (95% CI) in CFB [2]		-13.33 (-18.94, -7.72)		-11.11 (-35.27, 13.04)	
p-value [3]		<0.0001		0.325	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.7a
Change from Baseline in MC-QoL by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	54	102	4	9	
Mean (StdDev)	47.10 (21.011)	37.78 (21.809)	63.43 (6.783)	53.19 (25.065)	
Median	46.76	32.41	65.74	57.41	
Min, Max	12.0, 89.8	0.9, 91.7	53.7, 68.5	16.7, 92.6	
C7D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-6.14 (2.627)	-17.53 (2.019)	-2.99 (12.111)	-12.43 (9.597)	
95% CI [2]	-11.33, -0.95	-21.52, -13.54	-30.38, 24.41	-34.14, 9.28	
Difference (95% CI) in CFB [2]		-11.39 (-17.07, -5.71)		-9.44 (-33.08, 14.19)	
Hedges'G (95% CI) in CFB		-0.58 (-0.93, -0.24)		-0.32 (-1.72, 0.94)	
p-value [3]		<0.001		0.390	
					0.567

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-ecog-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.7a
Change from Baseline in MC-QoL by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	61	110	4	9	
Mean (StdDev)	63.02 (17.667)	66.79 (15.067)	82.64 (7.649)	70.68 (9.929)	
Median	63.89	69.44	81.94	75.00	
Min, Max	13.9, 100.0	33.3, 97.2	75.0, 91.7	55.6, 80.6	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.7a
Change from Baseline in MC-QoL by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	61	111	4	8	
Mean (StdDev)	54.53 (18.344)	53.33 (18.365)	72.92 (16.414)	55.56 (19.015)	
Median	52.78	55.56	66.67	55.56	
Min, Max	11.1, 100.0	11.1, 94.4	61.1, 97.2	25.0, 80.6	
C2D1 CFB					
n	59	108	4	8	
LS Mean (StdErr) [2]	-7.52 (2.022)	-12.73 (1.610)	-19.85 (10.147)	-22.55 (8.000)	
95% CI [2]	-11.51, -3.53	-15.91, -9.55	-43.25, 3.55	-41.00, -4.10	
Difference (95% CI) in CFB [2]		-5.21 (-9.64, -0.78)		-2.70 (-23.05, 17.66)	
p-value [3]		0.022		0.768	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.7a
Change from Baseline in MC-QoL by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	59	102	4	8	
Mean (StdDev)	54.33 (21.131)	49.44 (20.193)	66.67 (24.322)	55.21 (17.533)	
Median	55.56	47.22	62.50	62.50	
Min, Max	11.1, 100.0	5.6, 95.8	44.4, 97.2	22.2, 72.2	
C3D1 CFB					
n	57	101	4	8	
LS Mean (StdErr) [2]	-7.52 (2.349)	-16.08 (1.844)	-15.32 (12.886)	-15.73 (10.160)	
95% CI [2]	-12.16, -2.88	-19.72, -12.43	-45.03, 14.40	-39.16, 7.70	
Difference (95% CI) in CFB [2]		-8.56 (-13.70, -3.41)		-0.41 (-26.26, 25.44)	
p-value [3]		0.001		0.972	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-ecog-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.7a
Change from Baseline in MC-QoL by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	52	104	4	9	
Mean (StdDev)	54.49 (21.574)	49.76 (21.173)	81.94 (14.611)	58.64 (18.709)	
Median	55.56	50.00	86.11	61.11	
Min, Max	11.1, 97.2	8.3, 94.4	61.1, 94.4	33.3, 83.3	
C4D1 CFB					
n	50	102	4	9	
LS Mean (StdErr) [2]	-8.42 (2.660)	-15.65 (2.034)	1.46 (14.538)	-10.21 (11.520)	
95% CI [2]	-13.67, -3.16	-19.67, -11.63	-31.43, 34.35	-36.27, 15.85	
Difference (95% CI) in CFB [2]		-7.23 (-12.93, -1.53)		-11.67 (-40.04, 16.70)	
p-value [3]		0.013		0.377	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.7a
Change from Baseline in MC-QoL by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	56	99	4	9	
Mean (StdDev)	54.97 (21.773)	48.19 (21.183)	74.31 (15.937)	55.86 (21.130)	
Median	58.33	47.22	76.39	58.33	
Min, Max	11.1, 94.4	8.3, 100.0	55.6, 88.9	22.2, 83.3	
C5D1 CFB					
n	55	95	4	9	
LS Mean (StdErr) [2]	-6.76 (2.604)	-18.10 (2.073)	-12.29 (13.959)	-20.90 (11.061)	
95% CI [2]	-11.91, -1.62	-22.19, -14.00	-43.87, 19.29	-45.93, 4.12	
Difference (95% CI) in CFB [2]		-11.33 (-17.07, -5.60)		-8.61 (-35.85, 18.63)	
p-value [3]		<0.001		0.493	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.7a
Change from Baseline in MC-QoL by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	102	4	9	
Mean (StdDev)	54.78 (20.465)	46.02 (23.143)	81.25 (11.867)	53.70 (19.886)	
Median	54.17	44.44	86.11	63.89	
Min, Max	16.7, 97.2	2.8, 97.2	63.9, 88.9	25.0, 75.0	
C6D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-6.40 (2.773)	-18.90 (2.166)	4.65 (14.041)	-13.13 (11.127)	
95% CI [2]	-11.88, -0.92	-23.18, -14.62	-27.11, 36.42	-38.29, 12.04	
Difference (95% CI) in CFB [2]		-12.50 (-18.59, -6.41)		-17.78 (-45.18, 9.62)	
p-value [3]		<0.0001		0.176	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.7a
Change from Baseline in MC-QoL by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	54	102	4	9	
Mean (StdDev)	52.73 (21.020)	46.21 (22.949)	71.53 (13.679)	56.79 (21.432)	
Median	52.78	41.67	70.83	58.33	
Min, Max	13.9, 97.2	0.0, 100.0	55.6, 88.9	25.0, 86.1	
C7D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-6.12 (2.786)	-17.29 (2.142)	-10.07 (14.097)	-14.24 (11.171)	
95% CI [2]	-11.63, -0.62	-21.52, -13.06	-41.96, 21.82	-39.51, 11.03	
Difference (95% CI) in CFB [2]		-11.16 (-17.19, -5.14)		-4.17 (-31.68, 23.34)	
Hedges'G (95% CI) in CFB		-0.53 (-0.88, -0.20)		-0.12 (-1.47, 1.18)	
p-value [3]		<0.001		0.740	
					0.400

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.7a
Change from Baseline in MC-QoL by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	61	110	4	9	
Mean (StdDev)	54.57 (22.452)	56.67 (21.286)	79.86 (14.232)	65.43 (18.948)	
Median	52.78	56.94	81.94	63.89	
Min, Max	13.9, 97.2	5.6, 100.0	61.1, 94.4	27.8, 94.4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.7a
Change from Baseline in MC-QoL by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	61	111	4	8	
Mean (StdDev)	46.63 (22.493)	44.09 (24.190)	69.44 (11.340)	52.08 (22.846)	
Median	50.00	41.67	65.28	50.00	
Min, Max	2.8, 91.7	0.0, 100.0	61.1, 86.1	16.7, 94.4	
C2D1 CFB					
n	59	108	4	8	
LS Mean (StdErr) [2]	-6.91 (2.242)	-12.09 (1.785)	-11.48 (11.576)	-10.99 (9.127)	
95% CI [2]	-11.34, -2.48	-15.62, -8.57	-38.17, 15.22	-32.04, 10.06	
Difference (95% CI) in CFB [2]		-5.18 (-10.09, -0.27)		0.49 (-22.73, 23.71)	
p-value [3]		0.039		0.962	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.7a
Change from Baseline in MC-QoL by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	59	101	4	8	
Mean (StdDev)	47.08 (23.663)	40.02 (23.718)	69.44 (6.415)	46.53 (28.512)	
Median	44.44	36.11	69.44	48.61	
Min, Max	5.6, 88.9	0.0, 100.0	63.9, 75.0	13.9, 94.4	
C3D1 CFB					
n	57	101	4	8	
LS Mean (StdErr) [2]	-6.40 (2.520)	-15.81 (1.979)	-12.46 (12.303)	-21.77 (9.700)	
95% CI [2]	-11.38, -1.43	-19.72, -11.90	-40.83, 15.91	-44.14, 0.60	
Difference (95% CI) in CFB [2]		-9.40 (-14.92, -3.88)		-9.31 (-33.99, 15.37)	
p-value [3]		<0.001		0.410	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.7a
Change from Baseline in MC-QoL by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	52	104	4	9	
Mean (StdDev)	45.30 (22.896)	39.77 (24.077)	72.22 (6.001)	56.17 (29.291)	
Median	45.83	36.11	70.83	55.56	
Min, Max	8.3, 94.4	0.0, 97.2	66.7, 80.6	11.1, 94.4	
C4D1 CFB					
n	50	102	4	9	
LS Mean (StdErr) [2]	-8.22 (2.862)	-16.56 (2.188)	-12.99 (12.984)	-16.04 (10.289)	
95% CI [2]	-13.88, -2.57	-20.88, -12.23	-42.36, 16.39	-39.32, 7.23	
Difference (95% CI) in CFB [2]		-8.33 (-14.46, -2.20)		-3.06 (-28.39, 22.28)	
p-value [3]		0.008		0.791	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.7a
Change from Baseline in MC-QoL by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	55	100	4	9	
Mean (StdDev)	44.09 (23.806)	37.38 (23.596)	72.22 (11.785)	56.79 (34.165)	
Median	44.44	36.11	73.61	61.11	
Min, Max	0.0, 94.4	0.0, 100.0	58.3, 83.3	8.3, 97.2	
C5D1 CFB					
n	54	96	4	9	
LS Mean (StdErr) [2]	-7.40 (2.994)	-19.03 (2.362)	-13.40 (15.802)	-15.90 (12.521)	
95% CI [2]	-13.32, -1.48	-23.70, -14.37	-49.15, 22.34	-44.23, 12.42	
Difference (95% CI) in CFB [2]		-11.63 (-18.23, -5.04)		-2.50 (-33.34, 28.34)	
p-value [3]		<0.001		0.859	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.7a
Change from Baseline in MC-QoL by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	102	4	9	
Mean (StdDev)	47.99 (23.399)	36.22 (26.008)	72.22 (10.143)	57.72 (27.631)	
Median	47.22	31.94	72.22	55.56	
Min, Max	0.0, 94.4	0.0, 100.0	61.1, 83.3	16.7, 94.4	
C6D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-4.90 (3.078)	-20.12 (2.404)	-1.67 (12.339)	-6.39 (9.778)	
95% CI [2]	-10.98, 1.18	-24.87, -15.37	-29.58, 26.25	-28.51, 15.73	
Difference (95% CI) in CFB [2]		-15.22 (-21.99, -8.46)		-4.72 (-28.80, 19.36)	
p-value [3]		<0.0001		0.668	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.7a
Change from Baseline in MC-QoL by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	54	102	4	9	
Mean (StdDev)	44.75 (25.651)	35.24 (25.949)	73.61 (6.612)	53.09 (30.696)	
Median	44.44	30.56	73.61	55.56	
Min, Max	0.0, 97.2	0.0, 100.0	66.7, 80.6	11.1, 97.2	
C7D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-5.02 (3.235)	-17.77 (2.487)	-5.83 (11.488)	-16.11 (9.103)	
95% CI [2]	-11.41, 1.37	-22.69, -12.86	-31.82, 20.15	-36.70, 4.48	
Difference (95% CI) in CFB [2]		-12.75 (-19.75, -5.76)		-10.28 (-32.70, 12.14)	
Hedges'G (95% CI) in CFB		-0.52 (-0.87, -0.19)		-0.36 (-1.78, 0.89)	
p-value [3]		<0.001		0.327	
					0.610

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.7a
Change from Baseline in MC-QoL by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	61	110	4	9	
Mean (StdDev)	50.30 (22.902)	50.49 (22.931)	51.04 (7.887)	62.96 (20.565)	
Median	50.00	50.00	47.92	58.33	
Min, Max	0.0, 100.0	0.0, 100.0	45.8, 62.5	33.3, 100.0	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.7a
Change from Baseline in MC-QoL by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	61	111	4	8	
Mean (StdDev)	42.28 (22.475)	38.81 (24.185)	48.96 (10.417)	55.21 (29.103)	
Median	41.67	33.33	47.92	68.75	
Min, Max	0.0, 91.7	0.0, 100.0	37.5, 62.5	8.3, 91.7	
C2D1 CFB					
n	59	108	4	8	
LS Mean (StdErr) [2]	-6.49 (2.176)	-11.09 (1.732)	-13.48 (12.218)	-12.87 (9.633)	
95% CI [2]	-10.79, -2.20	-14.51, -7.67	-41.65, 14.69	-35.08, 9.35	
Difference (95% CI) in CFB [2]		-4.60 (-9.37, 0.17)		0.61 (-23.90, 25.12)	
p-value [3]		0.059		0.955	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.8.2.7a
Change from Baseline in MC-QoL by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	59	102	4	8	
Mean (StdDev)	41.58 (23.296)	34.08 (22.288)	41.67 (6.804)	47.92 (27.906)	
Median	37.50	33.33	41.67	47.92	
Min, Max	0.0, 91.7	0.0, 95.8	33.3, 50.0	8.3, 91.7	
C3D1 CFB					
n	57	101	4	8	
LS Mean (StdErr) [2]	-7.45 (2.473)	-15.82 (1.942)	-8.15 (12.280)	-12.56 (9.682)	
95% CI [2]	-12.33, -2.56	-19.66, -11.99	-36.47, 20.17	-34.89, 9.77	
Difference (95% CI) in CFB [2]		-8.37 (-13.79, -2.96)		-4.41 (-29.05, 20.22)	
p-value [3]		0.003		0.690	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.7a
Change from Baseline in MC-QoL by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	52	104	4	9	
Mean (StdDev)	42.15 (24.094)	33.72 (23.180)	52.08 (15.404)	55.09 (32.057)	
Median	43.75	29.17	45.83	58.33	
Min, Max	0.0, 91.7	0.0, 95.8	41.7, 75.0	0.0, 95.8	
C4D1 CFB					
n	50	102	4	9	
LS Mean (StdErr) [2]	-9.21 (2.847)	-18.36 (2.176)	5.00 (15.893)	-5.83 (12.593)	
95% CI [2]	-14.84, -3.58	-22.67, -14.06	-30.95, 40.95	-34.32, 22.65	
Difference (95% CI) in CFB [2]		-9.15 (-15.25, -3.05)		-10.83 (-41.85, 20.18)	
p-value [3]		0.004		0.450	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.7a
Change from Baseline in MC-QoL by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	56	100	4	9	
Mean (StdDev)	39.88 (24.655)	30.79 (23.413)	42.71 (11.968)	51.85 (28.876)	
Median	37.50	25.00	39.58	58.33	
Min, Max	0.0, 95.8	0.0, 91.7	33.3, 58.3	8.3, 91.7	
C5D1 CFB					
n	55	96	4	9	
LS Mean (StdErr) [2]	-10.18 (2.926)	-20.78 (2.317)	-1.35 (14.574)	-9.27 (11.548)	
95% CI [2]	-15.96, -4.39	-25.36, -16.20	-34.32, 31.61	-35.40, 16.85	
Difference (95% CI) in CFB [2]		-10.61 (-17.04, -4.17)		-7.92 (-36.36, 20.52)	
p-value [3]		0.001		0.545	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.7a
Change from Baseline in MC-QoL by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	102	4	9	
Mean (StdDev)	41.74 (24.703)	30.31 (23.410)	47.92 (22.948)	51.85 (28.268)	
Median	37.50	27.08	45.83	45.83	
Min, Max	0.0, 100.0	0.0, 91.7	25.0, 75.0	8.3, 95.8	
C6D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-7.92 (3.019)	-21.45 (2.358)	6.77 (16.427)	-5.73 (13.017)	
95% CI [2]	-13.88, -1.95	-26.11, -16.79	-30.39, 43.93	-35.17, 23.72	
Difference (95% CI) in CFB [2]		-13.54 (-20.17, -6.90)		-12.50 (-44.56, 19.56)	
p-value [3]		<0.0001		0.401	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.7a
Change from Baseline in MC-QoL by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	54	102	4	9	
Mean (StdDev)	38.97 (25.991)	29.98 (25.409)	46.88 (18.122)	50.93 (32.327)	
Median	33.33	25.00	47.92	45.83	
Min, Max	0.0, 100.0	0.0, 95.8	29.2, 62.5	4.2, 95.8	
C7D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-7.72 (3.137)	-17.81 (2.411)	8.23 (15.228)	-5.52 (12.067)	
95% CI [2]	-13.92, -1.52	-22.57, -13.04	-26.22, 42.68	-32.82, 21.78	
Difference (95% CI) in CFB [2]		-10.09 (-16.88, -3.30)		-13.75 (-43.47, 15.97)	
Hedges'G (95% CI) in CFB		-0.43 (-0.77, -0.09)		-0.37 (-1.79, 0.88)	
p-value [3]		0.004		0.323	
					0.777

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.7a
Change from Baseline in MC-QoL by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	61	110	4	9	
Mean (StdDev)	64.34 (20.979)	56.82 (22.212)	41.67 (35.355)	62.04 (20.031)	
Median	66.67	58.33	45.83	58.33	
Min, Max	8.3, 100.0	8.3, 100.0	0.0, 75.0	33.3, 91.7	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-ecog-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.7a
Change from Baseline in MC-QoL by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	61	111	4	8	
Mean (StdDev)	55.87 (19.623)	40.84 (18.530)	41.67 (34.021)	47.92 (19.288)	
Median	58.33	41.67	41.67	50.00	
Min, Max	0.0, 91.7	0.0, 83.3	0.0, 83.3	16.7, 83.3	
C2D1 CFB					
n	59	108	4	8	
LS Mean (StdErr) [2]	-6.37 (2.919)	-13.23 (2.323)	2.70 (18.221)	-7.84 (14.366)	
95% CI [2]	-12.13, -0.61	-17.82, -8.64	-39.32, 44.71	-40.97, 25.29	
Difference (95% CI) in CFB [2]		-6.86 (-13.26, -0.46)		-10.54 (-47.09, 26.01)	
p-value [3]		0.036		0.525	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.7a
Change from Baseline in MC-QoL by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	59	102	4	8	
Mean (StdDev)	52.68 (22.018)	38.32 (19.736)	39.58 (30.713)	52.08 (14.605)	
Median	58.33	33.33	41.67	58.33	
Min, Max	0.0, 100.0	0.0, 91.7	0.0, 75.0	25.0, 66.7	
C3D1 CFB					
n	57	101	4	8	
LS Mean (StdErr) [2]	-9.41 (3.412)	-15.77 (2.679)	3.80 (15.322)	0.12 (12.081)	
95% CI [2]	-16.15, -2.67	-21.06, -10.48	-31.53, 39.13	-27.74, 27.98	
Difference (95% CI) in CFB [2]		-6.36 (-13.83, 1.11)		-3.68 (-34.41, 27.06)	
p-value [3]		0.095		0.790	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-ecog-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.7a
Change from Baseline in MC-QoL by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	52	104	4	9	
Mean (StdDev)	55.29 (21.833)	36.22 (20.438)	43.75 (37.500)	50.00 (22.438)	
Median	58.33	33.33	41.67	41.67	
Min, Max	16.7, 100.0	0.0, 100.0	0.0, 91.7	25.0, 83.3	
C4D1 CFB					
n	50	102	4	9	
LS Mean (StdErr) [2]	-7.03 (3.614)	-18.25 (2.762)	5.62 (19.729)	-6.04 (15.633)	
95% CI [2]	-14.17, 0.11	-23.71, -12.79	-39.00, 50.25	-41.41, 29.32	
Difference (95% CI) in CFB [2]		-11.22 (-18.96, -3.48)		-11.67 (-50.17, 26.83)	
p-value [3]		0.005		0.510	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-ecog-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.7a
Change from Baseline in MC-QoL by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	56	99	4	9	
Mean (StdDev)	54.02 (25.574)	36.45 (19.941)	45.83 (33.679)	45.37 (23.976)	
Median	58.33	33.33	54.17	41.67	
Min, Max	8.3, 100.0	0.0, 100.0	0.0, 75.0	16.7, 91.7	
C5D1 CFB					
n	55	95	4	9	
LS Mean (StdErr) [2]	-7.14 (3.483)	-17.03 (2.774)	2.29 (19.066)	-11.88 (15.108)	
95% CI [2]	-14.03, -0.26	-22.51, -11.55	-40.84, 45.42	-46.05, 22.30	
Difference (95% CI) in CFB [2]		-9.89 (-17.56, -2.21)		-14.17 (-51.37, 23.04)	
p-value [3]		0.012		0.411	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-ecog-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.7a
Change from Baseline in MC-QoL by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	102	4	9	
Mean (StdDev)	52.31 (24.679)	36.85 (22.077)	43.75 (29.950)	55.56 (27.639)	
Median	54.17	33.33	54.17	58.33	
Min, Max	0.0, 100.0	0.0, 91.7	0.0, 66.7	8.3, 91.7	
C6D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-8.21 (3.608)	-17.47 (2.818)	6.67 (19.061)	-0.83 (15.104)	
95% CI [2]	-15.34, -1.08	-23.04, -11.90	-36.45, 49.78	-35.00, 33.33	
Difference (95% CI) in CFB [2]		-9.26 (-17.19, -1.33)		-7.50 (-44.70, 29.70)	
p-value [3]		0.022		0.659	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.7a
Change from Baseline in MC-QoL by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	54	102	4	9	
Mean (StdDev)	53.55 (23.492)	35.70 (20.459)	41.67 (29.659)	47.22 (27.639)	
Median	50.00	33.33	50.00	50.00	
Min, Max	0.0, 100.0	0.0, 91.7	0.0, 66.7	8.3, 91.7	
C7D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-6.76 (3.610)	-16.88 (2.775)	4.37 (18.847)	-9.79 (14.935)	
95% CI [2]	-13.90, 0.37	-22.36, -11.39	-38.26, 47.01	-43.58, 23.99	
Difference (95% CI) in CFB [2]		-10.12 (-17.93, -2.30)		-14.17 (-50.95, 22.61)	
Hedges'G (95% CI) in CFB		-0.37 (-0.72, -0.04)		-0.31 (-1.71, 0.95)	
p-value [3]		0.012		0.406	
					0.927

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	62	109	
Mean (StdDev)	59.26 (4.243)	68.06 (14.458)	58.21 (17.377)	58.45 (15.355)	
Median	60.19	73.61	58.33	58.33	
Min, Max	54.6, 63.0	40.7, 81.5	22.2, 97.2	26.9, 98.1	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	62	109	
Mean (StdDev)	47.53 (6.165)	52.04 (22.062)	50.28 (17.196)	45.62 (17.682)	
Median	49.07	53.24	52.78	44.44	
Min, Max	40.7, 52.8	21.3, 85.2	16.7, 92.6	14.8, 90.7	
C2D1 CFB					
n	3	10	60	106	
LS Mean (StdErr) [2]	-14.78 (9.543)	-22.11 (8.440)	-6.54 (1.714)	-11.65 (1.370)	
95% CI [2]	-36.37, 6.81	-41.21, -3.02	-9.92, -3.16	-14.36, -8.95	
Difference (95% CI) in CFB [2]		-7.33 (-32.00, 17.34)		-5.11 (-8.85, -1.38)	
p-value [3]		0.518		0.008	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	10	60	99	
Mean (StdDev)	50.93 (11.602)	47.22 (22.274)	49.48 (19.705)	41.54 (18.479)	
Median	50.00	44.44	49.07	37.96	
Min, Max	39.8, 63.0	23.1, 88.0	10.2, 88.0	1.9, 93.5	
C3D1 CFB					
n	3	10	58	99	
LS Mean (StdErr) [2]	-9.69 (11.884)	-23.37 (10.511)	-7.56 (2.051)	-15.33 (1.620)	
95% CI [2]	-36.57, 17.19	-47.15, 0.41	-11.61, -3.51	-18.53, -12.13	
Difference (95% CI) in CFB [2]		-13.68 (-44.40, 17.04)		-7.77 (-12.25, -3.30)	
p-value [3]		0.340		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	2	9	54	104	
Mean (StdDev)	50.46 (8.511)	40.74 (19.422)	50.12 (19.086)	42.69 (20.407)	
Median	50.46	30.56	47.69	40.74	
Min, Max	44.4, 56.5	18.5, 74.1	14.8, 87.0	2.8, 90.7	
C4D1 CFB					
n	2	9	52	102	
LS Mean (StdErr) [2]	-20.65 (13.811)	-29.23 (9.219)	-7.65 (2.285)	-15.41 (1.779)	
95% CI [2]	-53.31, 12.01	-51.03, -7.43	-12.16, -3.13	-18.93, -11.90	
Difference (95% CI) in CFB [2]		-8.58 (-42.97, 25.81)		-7.77 (-12.66, -2.87)	
p-value [3]		0.574		0.002	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-thpy-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	8	57	100	
Mean (StdDev)	46.91 (7.765)	37.15 (18.415)	49.00 (20.551)	41.04 (20.656)	
Median	50.93	33.80	49.07	37.04	
Min, Max	38.0, 51.9	18.5, 74.1	10.2, 88.0	4.6, 93.5	
C5D1 CFB					
n	3	8	56	96	
LS Mean (StdErr) [2]	-10.98 (11.289)	-25.10 (9.969)	-7.64 (2.414)	-17.56 (1.924)	
95% CI [2]	-37.67, 15.72	-48.67, -1.52	-12.41, -2.87	-21.36, -13.76	
Difference (95% CI) in CFB [2]		-14.12 (-44.80, 16.56)		-9.92 (-15.19, -4.65)	
p-value [3]		0.313		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	55	102	
Mean (StdDev)	47.84 (6.165)	37.24 (22.091)	50.69 (20.002)	39.80 (22.128)	
Median	46.30	29.63	50.00	36.11	
Min, Max	42.6, 54.6	13.9, 74.1	12.0, 89.8	2.8, 92.6	
C6D1 CFB					
n	3	9	54	98	
LS Mean (StdErr) [2]	-11.21 (12.548)	-28.10 (11.091)	-6.03 (2.544)	-18.28 (1.992)	
95% CI [2]	-40.14, 17.73	-53.68, -2.53	-11.06, -1.00	-22.21, -14.34	
Difference (95% CI) in CFB [2]		-16.90 (-50.04, 16.25)		-12.25 (-17.80, -6.70)	
p-value [3]		0.274		<0.0001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Total Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	8	55	103	
Mean (StdDev)	51.23 (9.503)	27.89 (12.986)	48.06 (21.222)	39.90 (22.747)	
Median	53.70	24.07	49.07	37.04	
Min, Max	40.7, 59.3	13.9, 48.1	12.0, 89.8	0.9, 92.6	
C7D1 CFB					
n	3	8	54	99	
LS Mean (StdErr) [2]	-7.29 (10.822)	-35.14 (9.557)	-6.21 (2.583)	-15.68 (1.992)	
95% CI [2]	-32.87, 18.30	-57.74, -12.54	-11.31, -1.10	-19.62, -11.75	
Difference (95% CI) in CFB [2]		-27.85 (-57.27, 1.56)		-9.48 (-15.01, -3.95)	
Hedges'G (95% CI) in CFB		-1.00 (-2.92, 0.34)		-0.48 (-0.83, -0.15)	
p-value [3]		0.060		<0.001	
					0.118

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.8.2.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	62	109	
Mean (StdDev)	53.70 (6.991)	73.33 (13.808)	64.74 (18.062)	66.51 (14.756)	
Median	52.78	76.39	65.28	69.44	
Min, Max	47.2, 61.1	47.2, 91.7	13.9, 100.0	33.3, 97.2	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	62	109	
Mean (StdDev)	46.30 (4.243)	59.17 (25.528)	56.11 (18.973)	52.96 (17.599)	
Median	47.22	59.72	56.94	55.56	
Min, Max	41.7, 50.0	11.1, 91.7	11.1, 100.0	11.1, 94.4	
C2D1 CFB					
n	3	10	60	106	
LS Mean (StdErr) [2]	-12.80 (12.820)	-24.99 (11.339)	-7.35 (1.932)	-12.46 (1.544)	
95% CI [2]	-41.80, 16.20	-50.64, 0.67	-11.17, -3.54	-15.51, -9.41	
Difference (95% CI) in CFB [2]		-12.19 (-45.33, 20.96)		-5.11 (-9.32, -0.90)	
p-value [3]		0.427		0.018	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	10	60	100	
Mean (StdDev)	50.00 (10.015)	54.17 (20.962)	55.37 (21.770)	49.43 (19.955)	
Median	52.78	48.61	55.56	47.22	
Min, Max	38.9, 58.3	27.8, 88.9	11.1, 100.0	5.6, 95.8	
C3D1 CFB					
n	3	10	58	99	
LS Mean (StdErr) [2]	-7.14 (11.219)	-26.25 (9.923)	-8.06 (2.339)	-15.54 (1.848)	
95% CI [2]	-32.52, 18.24	-48.69, -3.80	-12.68, -3.43	-19.19, -11.89	
Difference (95% CI) in CFB [2]		-19.10 (-48.11, 9.90)		-7.48 (-12.59, -2.38)	
p-value [3]		0.170		0.004	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.8.2.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	2	9	54	104	
Mean (StdDev)	47.22 (7.857)	52.78 (20.647)	56.79 (22.545)	50.27 (21.171)	
Median	47.22	47.22	61.11	50.00	
Min, Max	41.7, 52.8	30.6, 91.7	11.1, 97.2	8.3, 94.4	
C4D1 CFB					
n	2	9	52	102	
LS Mean (StdErr) [2]	-23.54 (12.988)	-27.34 (8.670)	-7.26 (2.635)	-14.52 (2.051)	
95% CI [2]	-54.25, 7.17	-47.84, -6.84	-12.46, -2.05	-18.57, -10.47	
Difference (95% CI) in CFB [2]		-3.80 (-36.14, 28.54)		-7.27 (-12.91, -1.62)	
p-value [3]		0.789		0.012	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	8	57	100	
Mean (StdDev)	42.59 (5.782)	51.39 (18.306)	56.97 (22.191)	48.63 (21.469)	
Median	44.44	44.44	61.11	50.00	
Min, Max	36.1, 47.2	30.6, 86.1	11.1, 94.4	8.3, 100.0	
C5D1 CFB					
n	3	8	56	96	
LS Mean (StdErr) [2]	-11.09 (10.524)	-21.05 (9.294)	-6.68 (2.627)	-17.54 (2.094)	
95% CI [2]	-35.98, 13.79	-43.02, 0.93	-11.87, -1.49	-21.68, -13.40	
Difference (95% CI) in CFB [2]		-9.95 (-38.56, 18.65)		-10.86 (-16.60, -5.12)	
p-value [3]		0.438		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.8.2.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	55	102	
Mean (StdDev)	41.67 (7.349)	45.06 (26.050)	57.42 (21.263)	46.79 (22.755)	
Median	44.44	38.89	55.56	45.83	
Min, Max	33.3, 47.2	16.7, 91.7	16.7, 97.2	2.8, 97.2	
C6D1 CFB					
n	3	9	54	98	
LS Mean (StdErr) [2]	-13.58 (14.355)	-29.98 (12.688)	-5.48 (2.730)	-17.80 (2.138)	
95% CI [2]	-46.68, 19.52	-59.24, -0.72	-10.88, -0.09	-22.02, -13.57	
Difference (95% CI) in CFB [2]		-16.41 (-54.33, 21.52)		-12.31 (-18.27, -6.36)	
p-value [3]		0.348		<0.0001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Symptoms

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	8	55	103	
Mean (StdDev)	48.15 (8.486)	38.54 (17.533)	54.34 (21.535)	47.73 (23.223)	
Median	50.00	37.50	55.56	41.67	
Min, Max	38.9, 55.6	13.9, 72.2	13.9, 97.2	0.0, 100.0	
C7D1 CFB					
n	3	8	54	99	
LS Mean (StdErr) [2]	-6.46 (13.155)	-33.08 (11.617)	-6.47 (2.759)	-15.78 (2.127)	
95% CI [2]	-37.57, 24.64	-60.55, -5.61	-11.92, -1.02	-19.99, -11.58	
Difference (95% CI) in CFB [2]		-26.62 (-62.37, 9.13)		-9.31 (-15.21, -3.40)	
Hedges'G (95% CI) in CFB		-0.79 (-2.61, 0.58)		-0.44 (-0.79, -0.11)	
p-value [3]		0.122		0.002	
					0.215

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	62	109	
Mean (StdDev)	64.81 (1.604)	67.78 (21.122)	55.71 (23.263)	56.37 (21.014)	
Median	63.89	70.83	54.17	55.56	
Min, Max	63.9, 66.7	27.8, 88.9	13.9, 97.2	5.6, 100.0	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	62	109	
Mean (StdDev)	45.37 (13.127)	55.28 (26.978)	48.16 (23.022)	43.65 (23.710)	
Median	50.00	51.39	50.00	44.44	
Min, Max	30.6, 55.6	16.7, 91.7	2.8, 91.7	0.0, 100.0	
C2D1 CFB					
n	3	10	60	106	
LS Mean (StdErr) [2]	-22.92 (7.183)	-19.74 (6.354)	-6.11 (2.257)	-11.59 (1.804)	
95% CI [2]	-39.17, -6.67	-34.11, -5.37	-10.56, -1.65	-15.15, -8.02	
Difference (95% CI) in CFB [2]		3.17 (-15.40, 21.75)		-5.48 (-10.40, -0.56)	
p-value [3]		0.708		0.029	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	10	60	99	
Mean (StdDev)	53.70 (15.299)	50.00 (30.146)	48.24 (23.977)	39.53 (23.274)	
Median	61.11	45.83	45.83	36.11	
Min, Max	36.1, 63.9	11.1, 94.4	5.6, 88.9	0.0, 100.0	
C3D1 CFB					
n	3	10	58	99	
LS Mean (StdErr) [2]	-11.11 (11.894)	-17.86 (10.520)	-6.72 (2.537)	-15.89 (2.004)	
95% CI [2]	-38.02, 15.79	-41.65, 5.94	-11.73, -1.71	-19.85, -11.93	
Difference (95% CI) in CFB [2]		-6.75 (-37.50, 24.00)		-9.17 (-14.71, -3.63)	
p-value [3]		0.632		0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.8.2.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	2	9	54	104	
Mean (StdDev)	47.22 (15.713)	38.89 (28.868)	47.22 (23.508)	41.27 (24.552)	
Median	47.22	27.78	47.22	38.89	
Min, Max	36.1, 58.3	5.6, 83.3	8.3, 94.4	0.0, 97.2	
C4D1 CFB					
n	2	9	52	102	
LS Mean (StdErr) [2]	-29.46 (13.721)	-33.70 (9.159)	-7.72 (2.806)	-14.98 (2.184)	
95% CI [2]	-61.91, 2.99	-55.36, -12.04	-13.26, -2.18	-19.29, -10.66	
Difference (95% CI) in CFB [2]		-4.24 (-38.41, 29.93)		-7.26 (-13.27, -1.25)	
p-value [3]		0.778		0.018	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.8.2.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	8	56	101	
Mean (StdDev)	44.44 (2.778)	34.72 (26.016)	46.08 (24.844)	39.32 (25.035)	
Median	44.44	30.56	47.22	36.11	
Min, Max	41.7, 47.2	5.6, 83.3	0.0, 94.4	0.0, 100.0	
C5D1 CFB					
n	3	8	55	97	
LS Mean (StdErr) [2]	-18.61 (10.804)	-27.18 (9.541)	-7.02 (3.041)	-17.41 (2.402)	
95% CI [2]	-44.16, 6.93	-49.74, -4.62	-13.03, -1.01	-22.16, -12.67	
Difference (95% CI) in CFB [2]		-8.56 (-37.93, 20.80)		-10.39 (-17.03, -3.76)	
p-value [3]		0.513		0.002	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.8.2.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	55	102	
Mean (StdDev)	46.30 (11.226)	37.96 (30.682)	49.85 (24.047)	37.96 (26.460)	
Median	52.78	22.22	50.00	33.33	
Min, Max	33.3, 52.8	8.3, 86.1	0.0, 94.4	0.0, 100.0	
C6D1 CFB					
n	3	9	54	98	
LS Mean (StdErr) [2]	-19.71 (12.320)	-29.58 (10.889)	-4.36 (3.085)	-18.39 (2.416)	
95% CI [2]	-48.11, 8.70	-54.69, -4.47	-10.45, 1.74	-23.17, -13.62	
Difference (95% CI) in CFB [2]		-9.87 (-42.42, 22.68)		-14.04 (-20.76, -7.31)	
p-value [3]		0.504		<0.0001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.8.2.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	8	55	103	
Mean (StdDev)	52.78 (20.031)	26.04 (22.367)	46.41 (26.242)	37.51 (26.881)	
Median	58.33	15.28	47.22	33.33	
Min, Max	30.6, 69.4	8.3, 69.4	0.0, 97.2	0.0, 100.0	
C7D1 CFB					
n	3	8	54	99	
LS Mean (StdErr) [2]	-12.08 (12.906)	-36.61 (11.397)	-4.83 (3.176)	-15.90 (2.449)	
95% CI [2]	-42.59, 18.44	-63.56, -9.66	-11.10, 1.45	-20.74, -11.06	
Difference (95% CI) in CFB [2]		-24.54 (-59.61, 10.54)		-11.07 (-17.87, -4.27)	
Hedges'G (95% CI) in CFB		-0.74 (-2.54, 0.64)		-0.46 (-0.80, -0.13)	
p-value [3]		0.142		0.002	
					0.375

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.8.2.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	62	109	
Mean (StdDev)	55.56 (2.406)	58.75 (19.881)	50.09 (22.746)	50.76 (23.145)	
Median	54.17	56.25	47.92	50.00	
Min, Max	54.2, 58.3	37.5, 100.0	0.0, 100.0	0.0, 100.0	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.8.2.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	62	109	
Mean (StdDev)	41.67 (7.217)	40.83 (25.215)	42.74 (22.431)	39.83 (24.822)	
Median	37.50	33.33	41.67	33.33	
Min, Max	37.5, 50.0	16.7, 100.0	0.0, 91.7	0.0, 100.0	
C2D1 CFB					
n	3	10	60	106	
LS Mean (StdErr) [2]	-13.99 (10.283)	-17.98 (9.095)	-6.17 (2.194)	-10.34 (1.754)	
95% CI [2]	-37.25, 9.27	-38.56, 2.59	-10.50, -1.84	-13.80, -6.87	
Difference (95% CI) in CFB [2]		-4.00 (-30.58, 22.59)		-4.17 (-8.95, 0.61)	
p-value [3]		0.742		0.087	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.8.2.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	10	60	100	
Mean (StdDev)	47.22 (18.789)	35.42 (25.250)	41.31 (22.851)	35.05 (22.765)	
Median	45.83	31.25	37.50	33.33	
Min, Max	29.2, 66.7	0.0, 95.8	0.0, 91.7	0.0, 95.8	
C3D1 CFB					
n	3	10	58	99	
LS Mean (StdErr) [2]	-8.78 (13.611)	-23.49 (12.038)	-7.73 (2.425)	-14.96 (1.915)	
95% CI [2]	-39.57, 22.01	-50.72, 3.74	-12.52, -2.94	-18.74, -11.18	
Difference (95% CI) in CFB [2]		-14.71 (-49.90, 20.48)		-7.23 (-12.53, -1.94)	
p-value [3]		0.369		0.008	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	2	9	54	104	
Mean (StdDev)	50.00 (5.893)	28.70 (16.724)	42.59 (24.006)	36.00 (25.057)	
Median	50.00	29.17	43.75	33.33	
Min, Max	45.8, 54.2	0.0, 58.3	0.0, 91.7	0.0, 95.8	
C4D1 CFB					
n	2	9	52	102	
LS Mean (StdErr) [2]	-8.11 (18.482)	-23.68 (12.336)	-8.87 (2.833)	-17.13 (2.205)	
95% CI [2]	-51.82, 35.59	-52.85, 5.49	-14.47, -3.27	-21.49, -12.77	
Difference (95% CI) in CFB [2]		-15.57 (-61.59, 30.45)		-8.26 (-14.33, -2.19)	
p-value [3]		0.450		0.008	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.8.2.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	8	57	101	
Mean (StdDev)	50.00 (18.162)	21.88 (14.217)	39.55 (24.246)	33.37 (24.941)	
Median	58.33	25.00	37.50	25.00	
Min, Max	29.2, 62.5	0.0, 41.7	0.0, 95.8	0.0, 91.7	
C5D1 CFB					
n	3	8	56	97	
LS Mean (StdErr) [2]	-4.25 (15.238)	-26.13 (13.456)	-10.59 (2.902)	-19.43 (2.300)	
95% CI [2]	-40.29, 31.78	-57.95, 5.69	-16.33, -4.86	-23.97, -14.88	
Difference (95% CI) in CFB [2]		-21.88 (-63.29, 19.54)		-8.84 (-15.16, -2.51)	
p-value [3]		0.252		0.006	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.8.2.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	55	102	
Mean (StdDev)	50.00 (11.024)	24.54 (13.412)	41.74 (24.955)	32.72 (25.092)	
Median	54.17	25.00	37.50	29.17	
Min, Max	37.5, 58.3	8.3, 45.8	0.0, 100.0	0.0, 95.8	
C6D1 CFB					
n	3	9	54	98	
LS Mean (StdErr) [2]	-3.97 (11.663)	-25.74 (10.309)	-8.21 (3.096)	-20.22 (2.424)	
95% CI [2]	-30.87, 22.92	-49.51, -1.96	-14.33, -2.09	-25.01, -15.42	
Difference (95% CI) in CFB [2]		-21.76 (-52.58, 9.05)		-12.01 (-18.76, -5.26)	
p-value [3]		0.142		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Emotions

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	8	55	103	
Mean (StdDev)	50.00 (18.162)	16.15 (9.563)	38.94 (25.825)	32.89 (27.021)	
Median	41.67	20.83	33.33	29.17	
Min, Max	37.5, 70.8	0.0, 25.0	0.0, 100.0	0.0, 95.8	
C7D1 CFB					
n	3	8	54	99	
LS Mean (StdErr) [2]	-3.73 (12.572)	-36.02 (11.102)	-7.85 (3.116)	-15.72 (2.403)	
95% CI [2]	-33.46, 25.99	-62.28, -9.77	-14.01, -1.70	-20.47, -10.97	
Difference (95% CI) in CFB [2]		-32.29 (-66.46, 1.88)		-7.87 (-14.54, -1.20)	
Hedges'G (95% CI) in CFB		-1.00 (-2.91, 0.35)		-0.33 (-0.67, -0.00)	
p-value [3]		0.061		0.021	
					0.070

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	62	109	
Mean (StdDev)	66.67 (14.434)	71.67 (26.701)	62.77 (22.770)	55.89 (21.194)	
Median	75.00	75.00	66.67	58.33	
Min, Max	50.0, 75.0	25.0, 100.0	0.0, 100.0	8.3, 100.0	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	62	109	
Mean (StdDev)	69.44 (4.811)	43.33 (22.498)	54.30 (20.894)	41.13 (18.295)	
Median	66.67	45.83	50.00	41.67	
Min, Max	66.7, 75.0	0.0, 75.0	0.0, 91.7	0.0, 83.3	
C2D1 CFB					
n	3	10	60	106	
LS Mean (StdErr) [2]	2.08 (17.554)	-28.87 (15.527)	-6.36 (2.843)	-11.81 (2.273)	
95% CI [2]	-37.63, 41.79	-63.99, 6.25	-11.98, -0.75	-16.30, -7.32	
Difference (95% CI) in CFB [2]		-30.95 (-76.34, 14.43)		-5.45 (-11.65, 0.75)	
p-value [3]		0.157		0.084	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	10	60	100	
Mean (StdDev)	52.78 (19.245)	41.67 (22.567)	51.81 (22.865)	39.08 (19.488)	
Median	41.67	41.67	58.33	37.50	
Min, Max	41.7, 75.0	8.3, 83.3	0.0, 100.0	0.0, 91.7	
C3D1 CFB					
n	3	10	58	99	
LS Mean (StdErr) [2]	-14.88 (19.571)	-31.04 (17.310)	-8.60 (3.293)	-13.71 (2.601)	
95% CI [2]	-59.15, 29.39	-70.20, 8.12	-15.10, -2.09	-18.85, -8.57	
Difference (95% CI) in CFB [2]		-16.16 (-66.75, 34.44)		-5.11 (-12.30, 2.08)	
p-value [3]		0.488		0.162	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	2	9	54	104	
Mean (StdDev)	70.83 (5.893)	34.26 (21.018)	53.86 (23.162)	37.58 (20.902)	
Median	70.83	25.00	58.33	33.33	
Min, Max	66.7, 75.0	8.3, 66.7	0.0, 100.0	0.0, 100.0	
C4D1 CFB					
n	2	9	52	102	
LS Mean (StdErr) [2]	-10.64 (21.909)	-32.57 (14.624)	-6.51 (3.486)	-15.86 (2.714)	
95% CI [2]	-62.44, 41.17	-67.15, 2.01	-13.39, 0.38	-21.22, -10.50	
Difference (95% CI) in CFB [2]		-21.93 (-76.48, 32.62)		-9.35 (-16.82, -1.89)	
p-value [3]		0.373		0.014	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-thpy-a.sas Date: 15:53/07AUG2023

Table 35.2.8.2.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	8	57	100	
Mean (StdDev)	61.11 (17.347)	32.29 (21.565)	53.07 (26.335)	37.58 (20.292)	
Median	66.67	29.17	58.33	33.33	
Min, Max	41.7, 75.0	8.3, 75.0	0.0, 100.0	0.0, 100.0	
C5D1 CFB					
n	3	8	56	96	
LS Mean (StdErr) [2]	-1.16 (18.831)	-28.94 (16.629)	-6.52 (3.386)	-15.21 (2.698)	
95% CI [2]	-45.69, 43.37	-68.26, 10.39	-13.21, 0.17	-20.54, -9.88	
Difference (95% CI) in CFB [2]		-27.78 (-78.96, 23.40)		-8.70 (-16.09, -1.30)	
p-value [3]		0.240		0.021	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	55	102	
Mean (StdDev)	66.67 (14.434)	37.04 (23.976)	50.91 (25.137)	38.48 (23.040)	
Median	75.00	33.33	50.00	33.33	
Min, Max	50.0, 75.0	8.3, 66.7	0.0, 100.0	0.0, 91.7	
C6D1 CFB					
n	3	9	54	98	
LS Mean (StdErr) [2]	6.91 (22.156)	-22.79 (19.583)	-8.68 (3.479)	-15.39 (2.724)	
95% CI [2]	-44.18, 58.00	-67.95, 22.37	-15.56, -1.81	-20.78, -10.01	
Difference (95% CI) in CFB [2]		-29.71 (-88.24, 28.83)		-6.71 (-14.30, 0.88)	
p-value [3]		0.276		0.083	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.8.2.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Skin

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	8	55	103	
Mean (StdDev)	58.33 (22.048)	25.00 (8.909)	52.42 (24.092)	37.54 (21.639)	
Median	66.67	25.00	50.00	33.33	
Min, Max	33.3, 75.0	8.3, 33.3	0.0, 100.0	0.0, 91.7	
C7D1 CFB					
n	3	8	54	99	
LS Mean (StdErr) [2]	-2.49 (11.597)	-35.13 (10.241)	-6.62 (3.549)	-14.55 (2.737)	
95% CI [2]	-29.91, 24.93	-59.34, -10.91	-13.63, 0.39	-19.96, -9.15	
Difference (95% CI) in CFB [2]		-32.64 (-64.16, -1.12)		-7.93 (-15.53, -0.34)	
Hedges'G (95% CI) in CFB		-1.09 (-3.05, 0.24)		-0.29 (-0.63, 0.04)	
p-value [3]		0.044		0.041	
					0.068

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-pp-thpy-a.sas Date: 15:53/07AUG2023

Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	54	113	11	6	
Mean (StdDev)	2.8 (1.13)	2.3 (1.08)	2.8 (1.17)	2.8 (1.33)	
Median	3.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	1, 4	1, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-age-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	54	113	11	6	
Mean (StdDev)	2.3 (1.00)	1.7 (0.91)	2.5 (1.21)	1.7 (0.82)	
Median	2.0	2.0	3.0	1.5	
Min, Max	0, 4	0, 4	0, 4	1, 3	
C2D1 CFB					
n	52	110	11	6	
LS Mean (StdErr) [2]	-0.37 (0.169)	-0.56 (0.125)	-0.64 (0.440)	-1.45 (0.642)	
95% CI [2]	-0.71, -0.04	-0.81, -0.31	-1.59, 0.31	-2.84, -0.07	
Difference (95% CI) in CFB [2]		-0.19 (-0.55, 0.17)		-0.82 (-1.90, 0.26)	
p-value [3]		0.308		0.125	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	53	104	10	6	
Mean (StdDev)	2.1 (1.13)	1.5 (0.96)	2.0 (1.15)	1.5 (0.55)	
Median	2.0	1.0	2.0	1.5	
Min, Max	0, 4	0, 4	0, 4	1, 2	
C3D1 CFB					
n	51	103	10	6	
LS Mean (StdErr) [2]	-0.57 (0.184)	-0.71 (0.135)	-0.81 (0.472)	-1.42 (0.682)	
95% CI [2]	-0.94, -0.21	-0.98, -0.44	-1.84, 0.21	-2.91, 0.07	
Difference (95% CI) in CFB [2]		-0.14 (-0.53, 0.26)		-0.61 (-1.77, 0.55)	
p-value [3]		0.488		0.276	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	49	107	7	6	
Mean (StdDev)	2.2 (1.06)	1.4 (1.05)	2.6 (1.27)	1.2 (0.41)	
Median	2.0	1.0	3.0	1.0	
Min, Max	0, 4	0, 4	1, 4	1, 2	
C4D1 CFB					
n	47	105	7	6	
LS Mean (StdErr) [2]	-0.51 (0.196)	-0.86 (0.142)	-0.47 (0.546)	-1.87 (0.895)	
95% CI [2]	-0.90, -0.13	-1.14, -0.58	-1.70, 0.77	-3.89, 0.16	
Difference (95% CI) in CFB [2]		-0.34 (-0.76, 0.07)		-1.40 (-3.16, 0.36)	
p-value [3]		0.099		0.105	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	51	103	9	5	
Mean (StdDev)	2.2 (1.13)	1.4 (0.99)	2.9 (1.45)	1.0 (0.00)	
Median	2.0	1.0	4.0	1.0	
Min, Max	0, 4	0, 4	1, 4	1, 1	
C5D1 CFB					
n	50	99	9	5	
LS Mean (StdErr) [2]	-0.48 (0.193)	-0.84 (0.144)	-0.64 (0.557)	-2.66 (0.855)	
95% CI [2]	-0.87, -0.10	-1.13, -0.56	-1.88, 0.60	-4.57, -0.76	
Difference (95% CI) in CFB [2]		-0.36 (-0.77, 0.05)		-2.02 (-3.58, -0.46)	
p-value [3]		0.088		0.016	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	50	105	8	6	
Mean (StdDev)	2.1 (1.15)	1.5 (1.05)	2.5 (1.51)	1.0 (0.63)	
Median	2.0	1.0	2.5	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 2	
C6D1 CFB					
n	49	101	8	6	
LS Mean (StdErr) [2]	-0.64 (0.192)	-0.81 (0.141)	-0.39 (0.513)	-1.96 (0.852)	
95% CI [2]	-1.02, -0.26	-1.09, -0.53	-1.53, 0.76	-3.86, -0.07	
Difference (95% CI) in CFB [2]		-0.18 (-0.59, 0.24)		-1.58 (-3.21, 0.06)	
p-value [3]		0.401		0.057	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	48	105	10	6	
Mean (StdDev)	2.2 (1.14)	1.3 (0.98)	2.9 (0.99)	1.0 (0.00)	
Median	2.0	1.0	3.0	1.0	
Min, Max	0, 4	0, 4	1, 4	1, 1	
C7D1 CFB					
n	47	101	10	6	
LS Mean (StdErr) [2]	-0.48 (0.184)	-0.83 (0.132)	-0.23 (0.528)	-2.07 (0.764)	
95% CI [2]	-0.85, -0.12	-1.09, -0.57	-1.38, 0.93	-3.73, -0.40	
Difference (95% CI) in CFB [2]		-0.34 (-0.73, 0.05)		-1.84 (-3.14, -0.54)	
Hedges'G (95% CI) in CFB		-0.26 (-0.62, 0.08)		-1.00 (-2.35, 0.01)	
p-value [3]		0.083		0.009	
					0.021

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	54	113	11	6	
Mean (StdDev)	2.4 (1.17)	2.1 (1.11)	3.0 (1.00)	2.0 (1.67)	
Median	2.0	2.0	3.0	1.5	
Min, Max	0, 4	0, 4	1, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-age-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	54	113	11	6	
Mean (StdDev)	2.1 (1.12)	1.5 (0.99)	2.8 (0.98)	1.3 (1.03)	
Median	2.0	1.0	3.0	1.0	
Min, Max	0, 4	0, 4	1, 4	0, 3	
C2D1 CFB					
n	52	110	11	6	
LS Mean (StdErr) [2]	-0.15 (0.180)	-0.55 (0.133)	-0.63 (0.496)	-1.50 (0.723)	
95% CI [2]	-0.51, 0.20	-0.81, -0.29	-1.71, 0.44	-3.06, 0.07	
Difference (95% CI) in CFB [2]		-0.40 (-0.78, -0.01)		-0.86 (-2.08, 0.35)	
p-value [3]		0.042		0.149	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	53	104	10	6	
Mean (StdDev)	2.1 (1.26)	1.4 (1.01)	2.4 (1.07)	1.2 (0.75)	
Median	2.0	1.0	3.0	1.0	
Min, Max	0, 4	0, 4	1, 4	0, 2	
C3D1 CFB					
n	51	103	10	6	
LS Mean (StdErr) [2]	-0.24 (0.194)	-0.59 (0.142)	-1.25 (0.513)	-1.73 (0.741)	
95% CI [2]	-0.63, 0.14	-0.87, -0.31	-2.37, -0.13	-3.34, -0.11	
Difference (95% CI) in CFB [2]		-0.35 (-0.76, 0.07)		-0.48 (-1.74, 0.78)	
p-value [3]		0.098		0.425	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	49	107	7	6	
Mean (StdDev)	2.1 (1.06)	1.3 (1.04)	2.4 (1.13)	1.2 (1.17)	
Median	2.0	1.0	3.0	1.0	
Min, Max	0, 4	0, 4	1, 4	0, 3	
C4D1 CFB					
n	47	105	7	6	
LS Mean (StdErr) [2]	-0.14 (0.197)	-0.71 (0.142)	-0.73 (0.374)	-0.93 (0.614)	
95% CI [2]	-0.52, 0.25	-0.99, -0.43	-1.58, 0.11	-2.32, 0.46	
Difference (95% CI) in CFB [2]		-0.58 (-0.99, -0.17)		-0.20 (-1.41, 1.01)	
p-value [3]		0.006		0.716	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	51	103	9	5	
Mean (StdDev)	2.0 (1.24)	1.4 (0.98)	2.8 (1.30)	0.8 (0.84)	
Median	2.0	1.0	3.0	1.0	
Min, Max	0, 4	0, 4	1, 4	0, 2	
C5D1 CFB					
n	50	99	9	5	
LS Mean (StdErr) [2]	-0.20 (0.195)	-0.59 (0.145)	-0.64 (0.370)	-1.66 (0.569)	
95% CI [2]	-0.58, 0.19	-0.88, -0.30	-1.47, 0.18	-2.93, -0.40	
Difference (95% CI) in CFB [2]		-0.40 (-0.81, 0.02)		-1.02 (-2.06, 0.02)	
p-value [3]		0.063		0.053	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	50	105	8	6	
Mean (StdDev)	2.1 (1.15)	1.5 (1.08)	2.6 (1.30)	0.5 (0.84)	
Median	2.0	1.0	2.5	0.0	
Min, Max	0, 4	0, 4	1, 4	0, 2	
C6D1 CFB					
n	49	101	8	6	
LS Mean (StdErr) [2]	-0.14 (0.197)	-0.54 (0.145)	-0.60 (0.420)	-2.22 (0.697)	
95% CI [2]	-0.53, 0.25	-0.82, -0.25	-1.53, 0.34	-3.77, -0.66	
Difference (95% CI) in CFB [2]		-0.40 (-0.82, 0.02)		-1.62 (-2.96, -0.28)	
p-value [3]		0.065		0.023	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	48	105	10	6	
Mean (StdDev)	2.0 (1.17)	1.4 (1.10)	3.0 (0.94)	0.7 (0.52)	
Median	2.0	1.0	3.0	1.0	
Min, Max	0, 4	0, 4	1, 4	0, 1	
C7D1 CFB					
n	47	101	10	6	
LS Mean (StdErr) [2]	-0.14 (0.204)	-0.48 (0.146)	-0.46 (0.583)	-1.97 (0.843)	
95% CI [2]	-0.54, 0.27	-0.77, -0.20	-1.73, 0.81	-3.80, -0.13	
Difference (95% CI) in CFB [2]		-0.35 (-0.78, 0.08)		-1.50 (-2.94, -0.07)	
Hedges'G (95% CI) in CFB		-0.24 (-0.59, 0.11)		-0.74 (-2.01, 0.28)	
p-value [3]		0.112		0.041	
					0.279

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	54	113	11	6	
Mean (StdDev)	2.3 (1.18)	2.4 (1.08)	2.2 (0.98)	1.8 (1.17)	
Median	2.0	2.0	3.0	1.5	
Min, Max	0, 4	0, 4	1, 3	1, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	54	113	11	6	
Mean (StdDev)	2.1 (1.12)	1.9 (1.06)	1.7 (0.90)	1.0 (1.10)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 3	0, 3	
C2D1 CFB					
n	52	110	11	6	
LS Mean (StdErr) [2]	-0.10 (0.162)	-0.39 (0.120)	-0.23 (0.268)	-0.51 (0.390)	
95% CI [2]	-0.42, 0.22	-0.63, -0.16	-0.81, 0.35	-1.35, 0.34	
Difference (95% CI) in CFB [2]		-0.30 (-0.64, 0.05)		-0.27 (-0.93, 0.38)	
p-value [3]		0.094		0.385	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	53	104	10	6	
Mean (StdDev)	2.1 (1.03)	1.8 (1.12)	1.4 (0.84)	1.3 (0.52)	
Median	2.0	2.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 3	1, 2	
C3D1 CFB					
n	51	103	10	6	
LS Mean (StdErr) [2]	-0.02 (0.177)	-0.45 (0.130)	-0.32 (0.503)	0.16 (0.728)	
95% CI [2]	-0.37, 0.33	-0.70, -0.19	-1.42, 0.78	-1.42, 1.75	
Difference (95% CI) in CFB [2]		-0.43 (-0.81, -0.05)		0.48 (-0.75, 1.72)	
p-value [3]		0.028		0.411	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	49	107	7	6	
Mean (StdDev)	2.2 (1.18)	1.8 (1.04)	1.7 (0.76)	1.2 (0.75)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	1, 3	0, 2	
C4D1 CFB					
n	47	105	7	6	
LS Mean (StdErr) [2]	-0.06 (0.188)	-0.51 (0.136)	-0.10 (0.617)	0.10 (1.013)	
95% CI [2]	-0.43, 0.31	-0.77, -0.24	-1.50, 1.30	-2.19, 2.39	
Difference (95% CI) in CFB [2]		-0.44 (-0.84, -0.05)		0.20 (-1.79, 2.19)	
p-value [3]		0.027		0.825	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-age-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	51	103	9	5	
Mean (StdDev)	2.0 (1.25)	1.8 (1.09)	2.0 (1.22)	1.0 (0.00)	
Median	2.0	2.0	1.0	1.0	
Min, Max	0, 4	0, 4	1, 4	1, 1	
C5D1 CFB					
n	50	99	9	5	
LS Mean (StdErr) [2]	-0.18 (0.201)	-0.53 (0.149)	0.02 (0.300)	-0.28 (0.461)	
95% CI [2]	-0.57, 0.22	-0.82, -0.23	-0.65, 0.69	-1.31, 0.74	
Difference (95% CI) in CFB [2]		-0.35 (-0.78, 0.08)		-0.30 (-1.15, 0.54)	
p-value [3]		0.109		0.439	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	50	105	8	6	
Mean (StdDev)	2.0 (1.19)	1.7 (1.15)	1.5 (1.20)	1.0 (0.63)	
Median	2.0	2.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 2	
C6D1 CFB					
n	49	101	8	6	
LS Mean (StdErr) [2]	-0.17 (0.192)	-0.55 (0.141)	-0.20 (0.600)	-0.44 (0.995)	
95% CI [2]	-0.55, 0.21	-0.83, -0.27	-1.53, 1.14	-2.65, 1.78	
Difference (95% CI) in CFB [2]		-0.37 (-0.78, 0.04)		-0.24 (-2.15, 1.67)	
p-value [3]		0.074		0.786	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	48	105	10	6	
Mean (StdDev)	1.9 (1.10)	1.7 (1.11)	1.9 (1.29)	0.8 (0.75)	
Median	2.0	2.0	1.5	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 2	
C7D1 CFB					
n	47	101	10	6	
LS Mean (StdErr) [2]	-0.31 (0.209)	-0.58 (0.149)	-0.21 (0.397)	-1.28 (0.574)	
95% CI [2]	-0.72, 0.11	-0.87, -0.28	-1.07, 0.66	-2.53, -0.03	
Difference (95% CI) in CFB [2]		-0.27 (-0.71, 0.17)		-1.07 (-2.05, -0.10)	
Hedges'G (95% CI) in CFB		-0.18 (-0.54, 0.16)		-0.77 (-2.06, 0.25)	
p-value [3]		0.226		0.034	
					0.560

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	54	113	11	6	
Mean (StdDev)	2.2 (1.18)	2.2 (1.22)	1.5 (1.13)	1.8 (1.17)	
Median	2.0	2.0	2.0	1.5	
Min, Max	0, 4	0, 4	0, 3	1, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	54	112	11	6	
Mean (StdDev)	1.8 (1.18)	1.5 (1.13)	1.3 (1.01)	1.7 (1.21)	
Median	2.0	1.0	1.0	1.5	
Min, Max	0, 4	0, 4	0, 3	0, 3	
C2D1 CFB					
n	52	109	11	6	
LS Mean (StdErr) [2]	-0.30 (0.183)	-0.51 (0.137)	-0.56 (0.460)	-0.65 (0.671)	
95% CI [2]	-0.66, 0.06	-0.78, -0.24	-1.55, 0.44	-2.10, 0.80	
Difference (95% CI) in CFB [2]		-0.22 (-0.61, 0.17)		-0.09 (-1.22, 1.04)	
p-value [3]		0.274		0.864	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	53	104	10	6	
Mean (StdDev)	1.9 (1.30)	1.6 (1.16)	1.1 (0.99)	1.0 (0.63)	
Median	2.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 3	0, 2	
C3D1 CFB					
n	51	103	10	6	
LS Mean (StdErr) [2]	-0.19 (0.206)	-0.49 (0.151)	-0.58 (0.428)	-1.40 (0.618)	
95% CI [2]	-0.60, 0.21	-0.79, -0.19	-1.52, 0.35	-2.74, -0.05	
Difference (95% CI) in CFB [2]		-0.30 (-0.74, 0.14)		-0.81 (-1.86, 0.24)	
p-value [3]		0.184		0.119	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	49	107	7	6	
Mean (StdDev)	1.9 (1.23)	1.5 (1.21)	1.0 (0.82)	1.2 (0.75)	
Median	2.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 2	0, 2	
C4D1 CFB					
n	47	105	7	6	
LS Mean (StdErr) [2]	-0.32 (0.195)	-0.53 (0.141)	-0.61 (0.679)	-1.31 (1.113)	
95% CI [2]	-0.71, 0.06	-0.81, -0.25	-2.14, 0.93	-3.83, 1.21	
Difference (95% CI) in CFB [2]		-0.21 (-0.62, 0.20)		-0.70 (-2.89, 1.49)	
p-value [3]		0.316		0.487	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	51	103	9	5	
Mean (StdDev)	1.9 (1.07)	1.5 (1.17)	1.4 (1.24)	0.6 (0.55)	
Median	2.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 1	
C5D1 CFB					
n	50	99	9	5	
LS Mean (StdErr) [2]	-0.22 (0.193)	-0.63 (0.143)	-0.32 (0.843)	-1.90 (1.295)	
95% CI [2]	-0.60, 0.16	-0.91, -0.35	-2.19, 1.56	-4.79, 0.98	
Difference (95% CI) in CFB [2]		-0.41 (-0.82, 0.00)		-1.59 (-3.95, 0.78)	
p-value [3]		0.050		0.166	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	50	105	8	6	
Mean (StdDev)	1.9 (1.21)	1.4 (1.15)	1.1 (0.83)	0.5 (0.55)	
Median	2.0	1.0	1.0	0.5	
Min, Max	0, 4	0, 4	0, 2	0, 1	
C6D1 CFB					
n	49	101	8	6	
LS Mean (StdErr) [2]	-0.15 (0.195)	-0.57 (0.143)	-0.56 (0.763)	-1.68 (1.267)	
95% CI [2]	-0.54, 0.23	-0.85, -0.29	-2.26, 1.14	-4.50, 1.15	
Difference (95% CI) in CFB [2]		-0.42 (-0.84, -0.00)		-1.11 (-3.55, 1.32)	
p-value [3]		0.049		0.332	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	48	105	10	6	
Mean (StdDev)	1.8 (1.12)	1.5 (1.26)	1.2 (0.79)	0.8 (0.41)	
Median	2.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 2	0, 1	
C7D1 CFB					
n	47	101	10	6	
LS Mean (StdErr) [2]	-0.12 (0.205)	-0.46 (0.147)	-0.56 (0.528)	-1.74 (0.764)	
95% CI [2]	-0.52, 0.29	-0.75, -0.17	-1.71, 0.59	-3.40, -0.07	
Difference (95% CI) in CFB [2]		-0.34 (-0.78, 0.09)		-1.18 (-2.48, 0.12)	
Hedges'G (95% CI) in CFB		-0.23 (-0.59, 0.11)		-0.64 (-1.89, 0.39)	
p-value [3]		0.122		0.072	
					0.652

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-age-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	54	113	11	6	
Mean (StdDev)	3.2 (0.90)	3.3 (0.87)	2.7 (0.90)	3.0 (0.89)	
Median	3.0	3.0	3.0	3.0	
Min, Max	1, 4	1, 4	1, 4	2, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-age-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	54	113	11	6	
Mean (StdDev)	2.9 (1.00)	2.7 (1.08)	2.5 (0.69)	2.5 (1.05)	
Median	3.0	3.0	2.0	2.5	
Min, Max	1, 4	0, 4	2, 4	1, 4	
C2D1 CFB					
n	52	110	11	6	
LS Mean (StdErr) [2]	-0.38 (0.151)	-0.53 (0.112)	-0.64 (0.398)	-1.37 (0.581)	
95% CI [2]	-0.68, -0.08	-0.75, -0.31	-1.50, 0.22	-2.62, -0.11	
Difference (95% CI) in CFB [2]		-0.15 (-0.48, 0.17)		-0.73 (-1.70, 0.25)	
p-value [3]		0.353		0.131	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-age-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	53	104	10	6	
Mean (StdDev)	2.8 (1.08)	2.5 (1.09)	2.1 (1.10)	2.3 (1.21)	
Median	3.0	3.0	2.0	2.5	
Min, Max	0, 4	0, 4	1, 4	1, 4	
C3D1 CFB					
n	51	103	10	6	
LS Mean (StdErr) [2]	-0.41 (0.175)	-0.70 (0.128)	-0.76 (0.523)	-1.10 (0.756)	
95% CI [2]	-0.75, -0.06	-0.95, -0.45	-1.90, 0.38	-2.75, 0.55	
Difference (95% CI) in CFB [2]		-0.29 (-0.66, 0.09)		-0.34 (-1.62, 0.94)	
p-value [3]		0.130		0.575	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	49	107	7	6	
Mean (StdDev)	2.8 (1.10)	2.6 (1.09)	2.7 (1.38)	1.3 (0.82)	
Median	3.0	3.0	3.0	1.5	
Min, Max	1, 4	0, 4	1, 4	0, 2	
C4D1 CFB					
n	47	105	7	6	
LS Mean (StdErr) [2]	-0.49 (0.179)	-0.65 (0.129)	-0.07 (0.775)	-2.27 (1.271)	
95% CI [2]	-0.85, -0.14	-0.91, -0.39	-1.82, 1.69	-5.14, 0.61	
Difference (95% CI) in CFB [2]		-0.16 (-0.53, 0.22)		-2.20 (-4.70, 0.30)	
p-value [3]		0.409		0.077	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	51	103	9	5	
Mean (StdDev)	2.7 (1.24)	2.5 (1.14)	3.0 (1.00)	1.2 (0.84)	
Median	3.0	3.0	3.0	1.0	
Min, Max	0, 4	0, 4	1, 4	0, 2	
C5D1 CFB					
n	50	99	9	5	
LS Mean (StdErr) [2]	-0.59 (0.176)	-0.78 (0.131)	0.23 (0.579)	-1.97 (0.889)	
95% CI [2]	-0.94, -0.24	-1.04, -0.52	-1.06, 1.52	-3.95, 0.01	
Difference (95% CI) in CFB [2]		-0.19 (-0.57, 0.19)		-2.20 (-3.82, -0.57)	
p-value [3]		0.315		0.013	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	50	105	8	6	
Mean (StdDev)	2.7 (1.10)	2.4 (1.19)	2.5 (1.20)	1.5 (0.84)	
Median	3.0	2.0	2.5	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 2	
C6D1 CFB					
n	49	101	8	6	
LS Mean (StdErr) [2]	-0.59 (0.185)	-0.86 (0.135)	-0.94 (0.683)	-1.82 (1.134)	
95% CI [2]	-0.96, -0.23	-1.12, -0.59	-2.46, 0.59	-4.35, 0.70	
Difference (95% CI) in CFB [2]		-0.26 (-0.66, 0.13)		-0.89 (-3.07, 1.29)	
p-value [3]		0.190		0.386	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	48	105	10	6	
Mean (StdDev)	2.6 (1.12)	2.4 (1.12)	2.6 (0.97)	1.5 (0.84)	
Median	3.0	3.0	2.5	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 2	
C7D1 CFB					
n	47	101	10	6	
LS Mean (StdErr) [2]	-0.61 (0.179)	-0.75 (0.128)	-0.45 (0.732)	-2.09 (1.059)	
95% CI [2]	-0.96, -0.26	-1.00, -0.49	-2.05, 1.14	-4.40, 0.21	
Difference (95% CI) in CFB [2]		-0.14 (-0.51, 0.24)		-1.64 (-3.44, 0.16)	
Hedges'G (95% CI) in CFB		-0.11 (-0.46, 0.24)		-0.64 (-1.89, 0.39)	
p-value [3]		0.478		0.070	
					0.034

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-age-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	54	113	11	6	
Mean (StdDev)	2.3 (1.08)	2.2 (1.06)	1.2 (0.87)	1.7 (0.52)	
Median	2.0	2.0	1.0	2.0	
Min, Max	0, 4	0, 4	0, 3	1, 2	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	54	113	11	6	
Mean (StdDev)	2.1 (1.08)	1.9 (1.00)	1.1 (0.70)	1.3 (0.52)	
Median	2.0	2.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 2	1, 2	
C2D1 CFB					
n	52	110	11	6	
LS Mean (StdErr) [2]	-0.16 (0.147)	-0.30 (0.109)	-0.05 (0.368)	-0.28 (0.537)	
95% CI [2]	-0.45, 0.13	-0.51, -0.08	-0.84, 0.75	-1.44, 0.88	
Difference (95% CI) in CFB [2]		-0.14 (-0.46, 0.18)		-0.23 (-1.13, 0.67)	
p-value [3]		0.381		0.595	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	53	104	10	6	
Mean (StdDev)	2.0 (1.07)	1.7 (0.97)	1.0 (0.94)	1.0 (0.89)	
Median	2.0	2.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 3	0, 2	
C3D1 CFB					
n	51	103	10	6	
LS Mean (StdErr) [2]	-0.27 (0.173)	-0.52 (0.127)	-0.15 (0.279)	-1.00 (0.403)	
95% CI [2]	-0.61, 0.07	-0.77, -0.27	-0.76, 0.45	-1.88, -0.13	
Difference (95% CI) in CFB [2]		-0.24 (-0.62, 0.13)		-0.85 (-1.53, -0.16)	
p-value [3]		0.194		0.019	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	49	107	7	6	
Mean (StdDev)	2.0 (1.17)	1.8 (1.17)	1.4 (1.27)	1.3 (0.82)	
Median	2.0	2.0	1.0	1.5	
Min, Max	0, 4	0, 4	0, 3	0, 2	
C4D1 CFB					
n	47	105	7	6	
LS Mean (StdErr) [2]	-0.22 (0.184)	-0.35 (0.133)	0.83 (0.266)	-0.07 (0.436)	
95% CI [2]	-0.58, 0.15	-0.61, -0.09	0.22, 1.43	-1.06, 0.91	
Difference (95% CI) in CFB [2]		-0.13 (-0.52, 0.25)		-0.90 (-1.76, -0.04)	
p-value [3]		0.497		0.041	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	51	103	9	5	
Mean (StdDev)	2.0 (1.22)	1.8 (1.10)	1.4 (1.33)	0.6 (0.89)	
Median	2.0	2.0	1.0	0.0	
Min, Max	0, 4	0, 4	0, 4	0, 2	
C5D1 CFB					
n	50	99	9	5	
LS Mean (StdErr) [2]	-0.35 (0.167)	-0.41 (0.124)	0.17 (0.584)	-1.26 (0.897)	
95% CI [2]	-0.68, -0.02	-0.66, -0.17	-1.13, 1.48	-3.26, 0.74	
Difference (95% CI) in CFB [2]		-0.06 (-0.42, 0.29)		-1.43 (-3.07, 0.20)	
p-value [3]		0.731		0.080	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	50	105	8	6	
Mean (StdDev)	2.0 (1.06)	1.7 (1.14)	1.1 (0.99)	0.5 (0.55)	
Median	2.0	2.0	1.0	0.5	
Min, Max	0, 4	0, 4	0, 3	0, 1	
C6D1 CFB					
n	49	101	8	6	
LS Mean (StdErr) [2]	-0.30 (0.167)	-0.45 (0.123)	0.01 (0.373)	-1.09 (0.619)	
95% CI [2]	-0.63, 0.03	-0.70, -0.21	-0.82, 0.84	-2.47, 0.29	
Difference (95% CI) in CFB [2]		-0.16 (-0.51, 0.20)		-1.10 (-2.29, 0.09)	
p-value [3]		0.393		0.067	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	48	105	10	6	
Mean (StdDev)	1.9 (1.05)	1.7 (1.09)	1.1 (1.10)	0.5 (0.55)	
Median	2.0	2.0	1.0	0.5	
Min, Max	0, 4	0, 4	0, 3	0, 1	
C7D1 CFB					
n	47	101	10	6	
LS Mean (StdErr) [2]	-0.39 (0.168)	-0.45 (0.120)	-0.17 (0.310)	-1.83 (0.448)	
95% CI [2]	-0.72, -0.06	-0.69, -0.21	-0.84, 0.51	-2.81, -0.86	
Difference (95% CI) in CFB [2]		-0.06 (-0.41, 0.30)		-1.67 (-2.43, -0.91)	
Hedges'G (95% CI) in CFB		-0.05 (-0.40, 0.30)		-1.54 (-3.08, -0.52)	
p-value [3]		0.744		<0.001	
					0.045

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	54	113	11	6	
Mean (StdDev)	2.9 (1.12)	2.8 (1.16)	2.0 (1.18)	3.0 (0.63)	
Median	3.0	3.0	2.0	3.0	
Min, Max	0, 4	0, 4	0, 4	2, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	54	112	11	6	
Mean (StdDev)	2.4 (1.11)	2.2 (1.12)	1.9 (0.94)	2.2 (0.75)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 3	1, 3	
C2D1 CFB					
n	52	109	11	6	
LS Mean (StdErr) [2]	-0.36 (0.147)	-0.43 (0.110)	-0.41 (0.352)	-0.91 (0.513)	
95% CI [2]	-0.65, -0.06	-0.65, -0.22	-1.17, 0.35	-2.01, 0.20	
Difference (95% CI) in CFB [2]		-0.08 (-0.39, 0.24)		-0.50 (-1.36, 0.36)	
p-value [3]		0.619		0.232	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	53	104	10	6	
Mean (StdDev)	2.3 (1.15)	2.1 (1.23)	1.8 (1.03)	2.2 (1.17)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 3	1, 4	
C3D1 CFB					
n	51	103	10	6	
LS Mean (StdErr) [2]	-0.55 (0.181)	-0.59 (0.132)	-0.41 (0.364)	-0.69 (0.526)	
95% CI [2]	-0.90, -0.19	-0.85, -0.33	-1.20, 0.38	-1.84, 0.46	
Difference (95% CI) in CFB [2]		-0.05 (-0.43, 0.34)		-0.28 (-1.17, 0.61)	
p-value [3]		0.816		0.506	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	49	107	7	6	
Mean (StdDev)	2.5 (1.19)	2.2 (1.24)	2.0 (0.82)	1.7 (0.82)	
Median	3.0	2.0	2.0	1.5	
Min, Max	0, 4	0, 4	1, 3	1, 3	
C4D1 CFB					
n	47	105	7	6	
LS Mean (StdErr) [2]	-0.36 (0.197)	-0.54 (0.143)	0.21 (0.688)	-0.29 (1.129)	
95% CI [2]	-0.75, 0.03	-0.82, -0.26	-1.35, 1.77	-2.85, 2.26	
Difference (95% CI) in CFB [2]		-0.18 (-0.60, 0.23)		-0.50 (-2.72, 1.72)	
p-value [3]		0.377		0.622	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	51	103	9	5	
Mean (StdDev)	2.5 (1.10)	2.3 (1.19)	2.0 (1.22)	1.6 (1.14)	
Median	3.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 3	
C5D1 CFB					
n	50	99	9	5	
LS Mean (StdErr) [2]	-0.32 (0.172)	-0.52 (0.128)	0.08 (0.596)	-0.99 (0.916)	
95% CI [2]	-0.66, 0.02	-0.77, -0.26	-1.25, 1.40	-3.03, 1.05	
Difference (95% CI) in CFB [2]		-0.19 (-0.56, 0.17)		-1.07 (-2.74, 0.61)	
p-value [3]		0.297		0.186	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	50	105	8	6	
Mean (StdDev)	2.6 (1.20)	2.1 (1.20)	1.6 (1.06)	1.7 (1.37)	
Median	3.0	2.0	1.5	1.5	
Min, Max	0, 4	0, 4	0, 3	0, 4	
C6D1 CFB					
n	49	101	8	6	
LS Mean (StdErr) [2]	-0.28 (0.183)	-0.64 (0.134)	-0.56 (0.686)	-0.77 (1.138)	
95% CI [2]	-0.64, 0.08	-0.90, -0.37	-2.08, 0.97	-3.30, 1.77	
Difference (95% CI) in CFB [2]		-0.36 (-0.75, 0.03)		-0.21 (-2.40, 1.98)	
p-value [3]		0.073		0.834	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	48	105	10	6	
Mean (StdDev)	2.3 (1.19)	2.2 (1.17)	2.0 (1.25)	1.2 (0.75)	
Median	2.5	2.0	2.5	1.0	
Min, Max	0, 4	0, 4	0, 3	0, 2	
C7D1 CFB					
n	47	101	10	6	
LS Mean (StdErr) [2]	-0.43 (0.179)	-0.43 (0.128)	-0.38 (0.519)	-2.11 (0.751)	
95% CI [2]	-0.79, -0.08	-0.69, -0.18	-1.51, 0.76	-3.75, -0.48	
Difference (95% CI) in CFB [2]		0.00 (-0.38, 0.38)		-1.74 (-3.01, -0.46)	
Hedges'G (95% CI) in CFB		0.00 (-0.35, 0.35)		-0.96 (-2.30, 0.05)	
p-value [3]		0.990		0.012	
					0.008

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	54	113	11	6	
Mean (StdDev)	2.5 (1.09)	2.7 (1.09)	1.5 (0.93)	2.7 (0.82)	
Median	2.0	3.0	2.0	3.0	
Min, Max	0, 4	0, 4	0, 3	1, 3	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	53	113	11	6	
Mean (StdDev)	2.2 (1.17)	2.1 (1.14)	1.5 (1.29)	1.5 (1.38)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	51	110	11	6	
LS Mean (StdErr) [2]	-0.21 (0.140)	-0.53 (0.103)	-0.03 (0.570)	-1.57 (0.831)	
95% CI [2]	-0.48, 0.07	-0.74, -0.33	-1.26, 1.20	-3.37, 0.22	
Difference (95% CI) in CFB [2]		-0.33 (-0.63, -0.03)		-1.55 (-2.94, -0.15)	
p-value [3]		0.033		0.033	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	53	104	10	6	
Mean (StdDev)	2.3 (1.18)	1.9 (1.20)	1.4 (0.97)	1.7 (0.82)	
Median	2.0	2.0	1.0	1.5	
Min, Max	0, 4	0, 4	0, 3	1, 3	
C3D1 CFB					
n	51	103	10	6	
LS Mean (StdErr) [2]	-0.19 (0.143)	-0.70 (0.104)	0.37 (0.387)	-0.76 (0.560)	
95% CI [2]	-0.48, 0.09	-0.90, -0.49	-0.48, 1.21	-1.98, 0.46	
Difference (95% CI) in CFB [2]		-0.50 (-0.81, -0.20)		-1.12 (-2.08, -0.17)	
p-value [3]		0.001		0.024	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	49	107	7	6	
Mean (StdDev)	2.2 (1.20)	2.0 (1.20)	1.6 (0.79)	1.7 (0.82)	
Median	2.0	2.0	1.0	1.5	
Min, Max	0, 4	0, 4	1, 3	1, 3	
C4D1 CFB					
n	47	105	7	6	
LS Mean (StdErr) [2]	-0.21 (0.166)	-0.57 (0.120)	0.40 (0.344)	-1.40 (0.564)	
95% CI [2]	-0.54, 0.12	-0.81, -0.33	-0.38, 1.18	-2.68, -0.12	
Difference (95% CI) in CFB [2]		-0.36 (-0.71, -0.01)		-1.80 (-2.91, -0.69)	
p-value [3]		0.041		0.005	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	51	103	9	5	
Mean (StdDev)	2.1 (1.23)	2.0 (1.19)	2.1 (1.17)	1.4 (0.55)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	1, 4	1, 2	
C5D1 CFB					
n	50	99	9	5	
LS Mean (StdErr) [2]	-0.30 (0.165)	-0.67 (0.123)	0.71 (0.361)	-1.18 (0.554)	
95% CI [2]	-0.63, 0.03	-0.91, -0.43	-0.10, 1.51	-2.42, 0.05	
Difference (95% CI) in CFB [2]		-0.37 (-0.72, -0.02)		-1.89 (-2.90, -0.88)	
p-value [3]		0.041		0.002	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	50	105	8	6	
Mean (StdDev)	2.1 (1.23)	1.8 (1.25)	1.6 (1.06)	1.7 (1.21)	
Median	2.0	2.0	1.0	1.0	
Min, Max	0, 4	0, 4	1, 4	1, 4	
C6D1 CFB					
n	49	101	8	6	
LS Mean (StdErr) [2]	-0.29 (0.171)	-0.76 (0.125)	0.38 (0.540)	-0.94 (0.896)	
95% CI [2]	-0.63, 0.05	-1.01, -0.51	-0.82, 1.58	-2.94, 1.05	
Difference (95% CI) in CFB [2]		-0.47 (-0.83, -0.10)		-1.32 (-3.04, 0.40)	
p-value [3]		0.012		0.117	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	48	105	10	6	
Mean (StdDev)	2.2 (1.19)	1.8 (1.28)	1.3 (0.82)	1.3 (0.52)	
Median	2.0	2.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 3	1, 2	
C7D1 CFB					
n	47	101	10	6	
LS Mean (StdErr) [2]	-0.15 (0.173)	-0.77 (0.124)	0.37 (0.405)	-0.80 (0.586)	
95% CI [2]	-0.50, 0.19	-1.02, -0.53	-0.51, 1.25	-2.08, 0.48	
Difference (95% CI) in CFB [2]		-0.62 (-0.99, -0.25)		-1.17 (-2.17, -0.17)	
Hedges'G (95% CI) in CFB		-0.50 (-0.86, -0.16)		-0.83 (-2.13, 0.19)	
p-value [3]		0.001		0.025	
					0.354

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	54	113	11	6	
Mean (StdDev)	2.2 (1.30)	2.2 (1.43)	1.4 (1.36)	0.7 (0.82)	
Median	2.0	3.0	1.0	0.5	
Min, Max	0, 4	0, 4	0, 4	0, 2	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	54	113	11	6	
Mean (StdDev)	1.9 (1.39)	1.7 (1.39)	0.7 (1.01)	0.7 (1.21)	
Median	2.0	2.0	0.0	0.0	
Min, Max	0, 4	0, 4	0, 3	0, 3	
C2D1 CFB					
n	52	110	11	6	
LS Mean (StdErr) [2]	-0.33 (0.221)	-0.52 (0.163)	-0.46 (0.601)	-0.14 (0.876)	
95% CI [2]	-0.77, 0.10	-0.84, -0.19	-1.76, 0.84	-2.03, 1.75	
Difference (95% CI) in CFB [2]		-0.18 (-0.66, 0.29)		0.32 (-1.15, 1.79)	
p-value [3]		0.442		0.648	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	53	103	10	6	
Mean (StdDev)	1.9 (1.28)	1.7 (1.37)	0.9 (1.20)	0.0 (0.00)	
Median	2.0	1.0	0.5	0.0	
Min, Max	0, 4	0, 4	0, 3	0, 0	
C3D1 CFB					
n	51	103	10	6	
LS Mean (StdErr) [2]	-0.34 (0.237)	-0.57 (0.173)	-0.19 (0.520)	-0.58 (0.752)	
95% CI [2]	-0.81, 0.13	-0.92, -0.23	-1.32, 0.95	-2.22, 1.06	
Difference (95% CI) in CFB [2]		-0.23 (-0.74, 0.27)		-0.39 (-1.67, 0.89)	
p-value [3]		0.364		0.517	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	49	107	7	6	
Mean (StdDev)	2.0 (1.15)	1.6 (1.33)	1.1 (1.46)	0.8 (0.98)	
Median	2.0	1.0	0.0	0.5	
Min, Max	0, 4	0, 4	0, 3	0, 2	
C4D1 CFB					
n	47	105	7	6	
LS Mean (StdErr) [2]	-0.23 (0.247)	-0.66 (0.179)	-0.05 (0.612)	0.55 (1.004)	
95% CI [2]	-0.72, 0.26	-1.02, -0.31	-1.43, 1.33	-1.72, 2.82	
Difference (95% CI) in CFB [2]		-0.43 (-0.95, 0.09)		0.60 (-1.37, 2.57)	
p-value [3]		0.101		0.509	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	50	104	9	5	
Mean (StdDev)	2.0 (1.19)	1.5 (1.31)	1.4 (1.33)	0.4 (0.55)	
Median	2.0	1.0	1.0	0.0	
Min, Max	0, 4	0, 4	0, 3	0, 1	
C5D1 CFB					
n	49	100	9	5	
LS Mean (StdErr) [2]	-0.22 (0.233)	-0.80 (0.172)	0.09 (0.751)	-0.13 (1.154)	
95% CI [2]	-0.68, 0.24	-1.14, -0.46	-1.59, 1.76	-2.70, 2.44	
Difference (95% CI) in CFB [2]		-0.58 (-1.08, -0.09)		-0.22 (-2.32, 1.89)	
p-value [3]		0.022		0.823	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-age-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	50	105	8	6	
Mean (StdDev)	2.1 (1.26)	1.5 (1.34)	1.1 (1.13)	0.5 (0.84)	
Median	2.0	1.0	1.0	0.0	
Min, Max	0, 4	0, 4	0, 3	0, 2	
C6D1 CFB					
n	49	101	8	6	
LS Mean (StdErr) [2]	-0.13 (0.236)	-0.64 (0.173)	-0.15 (0.642)	-0.08 (1.065)	
95% CI [2]	-0.60, 0.34	-0.98, -0.29	-1.58, 1.28	-2.45, 2.30	
Difference (95% CI) in CFB [2]		-0.51 (-1.01, -0.00)		0.07 (-1.98, 2.12)	
p-value [3]		0.049		0.940	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	48	105	10	6	
Mean (StdDev)	1.9 (1.29)	1.5 (1.32)	0.9 (1.10)	0.3 (0.52)	
Median	2.0	1.0	0.5	0.0	
Min, Max	0, 4	0, 4	0, 3	0, 1	
C7D1 CFB					
n	47	101	10	6	
LS Mean (StdErr) [2]	-0.23 (0.240)	-0.65 (0.171)	0.28 (0.479)	0.39 (0.692)	
95% CI [2]	-0.71, 0.24	-0.99, -0.31	-0.76, 1.32	-1.12, 1.90	
Difference (95% CI) in CFB [2]		-0.42 (-0.93, 0.09)		0.11 (-1.07, 1.29)	
Hedges'G (95% CI) in CFB		-0.25 (-0.60, 0.10)		0.07 (-1.03, 1.19)	
p-value [3]		0.104		0.840	
					0.518

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-age-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	54	113	11	6	
Mean (StdDev)	2.7 (1.21)	2.6 (1.32)	1.6 (1.21)	3.2 (0.75)	
Median	3.0	3.0	2.0	3.0	
Min, Max	0, 4	0, 4	0, 4	2, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-age-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	54	113	11	6	
Mean (StdDev)	2.5 (1.18)	2.1 (1.32)	1.6 (1.36)	1.7 (1.03)	
Median	3.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 3	
C2D1 CFB					
n	52	110	11	6	
LS Mean (StdErr) [2]	-0.25 (0.181)	-0.49 (0.134)	0.36 (0.450)	-1.37 (0.655)	
95% CI [2]	-0.60, 0.11	-0.75, -0.22	-0.61, 1.33	-2.79, 0.05	
Difference (95% CI) in CFB [2]		-0.24 (-0.63, 0.15)		-1.73 (-2.83, -0.63)	
p-value [3]		0.222		0.005	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-age-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	53	103	10	6	
Mean (StdDev)	2.5 (1.15)	1.9 (1.30)	1.5 (1.18)	1.0 (0.89)	
Median	3.0	2.0	1.5	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 2	
C3D1 CFB					
n	51	103	10	6	
LS Mean (StdErr) [2]	-0.29 (0.187)	-0.69 (0.137)	-0.40 (0.324)	-2.82 (0.468)	
95% CI [2]	-0.66, 0.08	-0.96, -0.42	-1.10, 0.31	-3.84, -1.80	
Difference (95% CI) in CFB [2]		-0.40 (-0.80, -0.00)		-2.42 (-3.21, -1.62)	
p-value [3]		0.049		<0.0001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-age-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	49	107	7	6	
Mean (StdDev)	2.2 (1.26)	2.0 (1.37)	1.6 (1.62)	1.7 (0.82)	
Median	2.0	2.0	2.0	1.5	
Min, Max	0, 4	0, 4	0, 4	1, 3	
C4D1 CFB					
n	47	105	7	6	
LS Mean (StdErr) [2]	-0.37 (0.207)	-0.64 (0.150)	0.07 (0.521)	-1.73 (0.855)	
95% CI [2]	-0.78, 0.03	-0.93, -0.34	-1.11, 1.25	-3.67, 0.20	
Difference (95% CI) in CFB [2]		-0.26 (-0.69, 0.17)		-1.80 (-3.48, -0.12)	
p-value [3]		0.236		0.038	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-age-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	50	104	9	5	
Mean (StdDev)	2.3 (1.21)	1.8 (1.25)	1.8 (1.30)	0.8 (0.84)	
Median	2.5	2.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 2	
C5D1 CFB					
n	49	100	9	5	
LS Mean (StdErr) [2]	-0.38 (0.190)	-0.80 (0.140)	-0.22 (0.779)	-3.17 (1.196)	
95% CI [2]	-0.75, -0.00	-1.08, -0.53	-1.95, 1.52	-5.84, -0.51	
Difference (95% CI) in CFB [2]		-0.43 (-0.83, -0.02)		-2.96 (-5.14, -0.77)	
p-value [3]		0.040		0.013	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	50	105	8	6	
Mean (StdDev)	2.5 (1.25)	1.8 (1.33)	1.6 (1.06)	0.8 (0.75)	
Median	3.0	2.0	1.5	1.0	
Min, Max	0, 4	0, 4	0, 3	0, 2	
C6D1 CFB					
n	49	101	8	6	
LS Mean (StdErr) [2]	-0.12 (0.201)	-0.74 (0.147)	0.09 (0.418)	-2.19 (0.694)	
95% CI [2]	-0.52, 0.28	-1.03, -0.44	-0.84, 1.02	-3.74, -0.64	
Difference (95% CI) in CFB [2]		-0.62 (-1.05, -0.19)		-2.28 (-3.62, -0.95)	
p-value [3]		0.005		0.003	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-age-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	48	105	10	6	
Mean (StdDev)	2.3 (1.27)	1.8 (1.38)	1.8 (1.32)	1.0 (0.89)	
Median	2.5	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 2	
C7D1 CFB					
n	47	101	10	6	
LS Mean (StdErr) [2]	-0.46 (0.218)	-0.78 (0.155)	-0.23 (0.411)	-2.98 (0.594)	
95% CI [2]	-0.89, -0.03	-1.08, -0.47	-1.13, 0.66	-4.28, -1.69	
Difference (95% CI) in CFB [2]		-0.32 (-0.78, 0.14)		-2.75 (-3.76, -1.74)	
Hedges'G (95% CI) in CFB		-0.21 (-0.56, 0.14)		-1.92 (-3.60, -0.87)	
p-value [3]		0.170		<0.0001	
					0.001

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-age-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	54	113	11	6	
Mean (StdDev)	2.4 (1.33)	2.4 (1.10)	2.1 (1.58)	3.0 (0.89)	
Median	3.0	3.0	3.0	3.0	
Min, Max	0, 4	0, 4	0, 4	2, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-age-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	54	113	11	6	
Mean (StdDev)	2.1 (1.20)	1.8 (1.19)	1.8 (1.17)	1.8 (1.60)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	52	110	11	6	
LS Mean (StdErr) [2]	-0.11 (0.174)	-0.48 (0.129)	-0.57 (0.812)	-1.43 (1.184)	
95% CI [2]	-0.46, 0.23	-0.73, -0.23	-2.33, 1.18	-3.99, 1.12	
Difference (95% CI) in CFB [2]		-0.37 (-0.74, 0.01)		-0.86 (-2.85, 1.13)	
p-value [3]		0.054		0.365	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-age-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	53	103	10	6	
Mean (StdDev)	1.9 (1.41)	1.8 (1.13)	2.0 (1.33)	1.2 (0.75)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 2	
C3D1 CFB					
n	51	103	10	6	
LS Mean (StdErr) [2]	-0.34 (0.166)	-0.51 (0.122)	0.11 (0.686)	-1.40 (0.992)	
95% CI [2]	-0.66, -0.01	-0.75, -0.27	-1.39, 1.60	-3.56, 0.76	
Difference (95% CI) in CFB [2]		-0.18 (-0.53, 0.18)		-1.51 (-3.20, 0.18)	
p-value [3]		0.326		0.075	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	49	107	7	6	
Mean (StdDev)	2.1 (1.35)	1.8 (1.23)	1.9 (1.35)	1.0 (0.63)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 2	
C4D1 CFB					
n	47	105	7	6	
LS Mean (StdErr) [2]	-0.32 (0.202)	-0.63 (0.146)	-0.54 (0.778)	-2.04 (1.276)	
95% CI [2]	-0.72, 0.08	-0.92, -0.34	-2.30, 1.22	-4.93, 0.85	
Difference (95% CI) in CFB [2]		-0.31 (-0.74, 0.11)		-1.50 (-4.01, 1.01)	
p-value [3]		0.146		0.209	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	50	104	9	5	
Mean (StdDev)	2.0 (1.36)	1.7 (1.25)	2.3 (1.12)	1.0 (0.71)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 2	
C5D1 CFB					
n	49	100	9	5	
LS Mean (StdErr) [2]	-0.27 (0.196)	-0.77 (0.144)	-0.14 (0.836)	-2.16 (1.284)	
95% CI [2]	-0.66, 0.12	-1.05, -0.48	-2.00, 1.72	-5.02, 0.70	
Difference (95% CI) in CFB [2]		-0.50 (-0.92, -0.08)		-2.02 (-4.37, 0.32)	
p-value [3]		0.020		0.084	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	50	105	8	6	
Mean (StdDev)	2.2 (1.39)	1.6 (1.24)	2.4 (0.92)	0.8 (0.98)	
Median	2.0	2.0	2.0	0.5	
Min, Max	0, 4	0, 4	1, 4	0, 2	
C6D1 CFB					
n	49	101	8	6	
LS Mean (StdErr) [2]	0.00 (0.197)	-0.71 (0.145)	-0.11 (0.793)	-2.63 (1.317)	
95% CI [2]	-0.39, 0.39	-1.00, -0.43	-1.87, 1.66	-5.56, 0.31	
Difference (95% CI) in CFB [2]		-0.72 (-1.14, -0.30)		-2.52 (-5.05, 0.01)	
p-value [3]		<0.001		0.051	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	48	105	10	6	
Mean (StdDev)	2.0 (1.34)	1.7 (1.30)	2.2 (1.32)	1.0 (0.89)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 2	
C7D1 CFB					
n	47	101	10	6	
LS Mean (StdErr) [2]	-0.18 (0.196)	-0.64 (0.140)	-0.70 (0.813)	-2.91 (1.176)	
95% CI [2]	-0.57, 0.21	-0.91, -0.36	-2.47, 1.07	-5.47, -0.35	
Difference (95% CI) in CFB [2]		-0.46 (-0.87, -0.05)		-2.21 (-4.21, -0.21)	
Hedges'G (95% CI) in CFB		-0.33 (-0.69, 0.02)		-0.78 (-2.07, 0.24)	
p-value [3]		0.030		0.033	
					0.015

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	54	113	11	6	
Mean (StdDev)	1.8 (1.51)	1.9 (1.49)	1.5 (1.63)	1.8 (1.83)	
Median	2.0	2.0	1.0	1.5	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	54	113	11	6	
Mean (StdDev)	1.8 (1.45)	1.6 (1.45)	1.4 (1.80)	1.3 (1.75)	
Median	2.0	1.0	0.0	0.5	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	52	110	11	6	
LS Mean (StdErr) [2]	-0.02 (0.165)	-0.30 (0.122)	-0.30 (0.760)	-1.57 (1.108)	
95% CI [2]	-0.35, 0.30	-0.54, -0.06	-1.94, 1.35	-3.96, 0.82	
Difference (95% CI) in CFB [2]		-0.27 (-0.63, 0.08)		-1.27 (-3.13, 0.59)	
p-value [3]		0.129		0.163	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	53	103	10	6	
Mean (StdDev)	1.6 (1.54)	1.4 (1.42)	1.1 (1.66)	1.0 (1.26)	
Median	1.0	1.0	0.0	0.5	
Min, Max	0, 4	0, 4	0, 4	0, 3	
C3D1 CFB					
n	51	103	10	6	
LS Mean (StdErr) [2]	-0.24 (0.169)	-0.41 (0.124)	-0.32 (0.767)	-1.84 (1.110)	
95% CI [2]	-0.58, 0.09	-0.66, -0.17	-1.99, 1.35	-4.25, 0.58	
Difference (95% CI) in CFB [2]		-0.17 (-0.53, 0.20)		-1.52 (-3.40, 0.37)	
p-value [3]		0.370		0.105	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	49	107	7	6	
Mean (StdDev)	1.7 (1.32)	1.4 (1.39)	1.3 (1.60)	1.2 (1.60)	
Median	2.0	1.0	1.0	0.5	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	47	105	7	6	
LS Mean (StdErr) [2]	-0.18 (0.220)	-0.41 (0.159)	-0.24 (0.596)	-0.34 (0.978)	
95% CI [2]	-0.62, 0.25	-0.72, -0.09	-1.59, 1.11	-2.55, 1.87	
Difference (95% CI) in CFB [2]		-0.22 (-0.68, 0.24)		-0.10 (-2.02, 1.82)	
p-value [3]		0.342		0.909	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	50	103	9	5	
Mean (StdDev)	1.4 (1.39)	1.4 (1.36)	1.2 (1.64)	1.0 (1.73)	
Median	1.0	1.0	0.0	0.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	49	99	9	5	
LS Mean (StdErr) [2]	-0.26 (0.208)	-0.47 (0.153)	-0.18 (1.055)	-1.60 (1.621)	
95% CI [2]	-0.67, 0.15	-0.78, -0.17	-2.54, 2.17	-5.21, 2.01	
Difference (95% CI) in CFB [2]		-0.21 (-0.66, 0.23)		-1.41 (-4.37, 1.55)	
p-value [3]		0.349		0.313	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	50	105	8	6	
Mean (StdDev)	1.5 (1.40)	1.4 (1.45)	0.8 (1.16)	1.0 (1.55)	
Median	1.0	1.0	0.0	0.0	
Min, Max	0, 4	0, 4	0, 3	0, 3	
C6D1 CFB					
n	49	101	8	6	
LS Mean (StdErr) [2]	-0.26 (0.235)	-0.51 (0.172)	-0.43 (0.629)	-0.42 (1.044)	
95% CI [2]	-0.72, 0.21	-0.85, -0.17	-1.83, 0.97	-2.74, 1.91	
Difference (95% CI) in CFB [2]		-0.25 (-0.75, 0.25)		0.01 (-1.99, 2.02)	
p-value [3]		0.324		0.988	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	48	105	10	6	
Mean (StdDev)	1.6 (1.46)	1.4 (1.44)	1.1 (1.20)	0.8 (1.33)	
Median	1.0	1.0	1.0	0.0	
Min, Max	0, 4	0, 4	0, 4	0, 3	
C7D1 CFB					
n	47	101	10	6	
LS Mean (StdErr) [2]	-0.09 (0.231)	-0.38 (0.165)	-0.13 (0.542)	-1.26 (0.784)	
95% CI [2]	-0.55, 0.36	-0.70, -0.05	-1.32, 1.05	-2.97, 0.45	
Difference (95% CI) in CFB [2]		-0.28 (-0.77, 0.21)		-1.12 (-2.46, 0.21)	
Hedges'G (95% CI) in CFB		-0.17 (-0.52, 0.17)		-0.59 (-1.83, 0.44)	
p-value [3]		0.254		0.091	
					0.414

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	54	113	11	6	
Mean (StdDev)	2.2 (1.33)	2.4 (1.18)	2.1 (1.30)	2.0 (1.26)	
Median	2.0	3.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	54	113	11	6	
Mean (StdDev)	1.9 (1.22)	1.9 (1.18)	1.3 (1.27)	1.8 (0.98)	
Median	2.0	2.0	1.0	2.0	
Min, Max	0, 4	0, 4	0, 3	0, 3	
C2D1 CFB					
n	52	110	11	6	
LS Mean (StdErr) [2]	-0.21 (0.145)	-0.46 (0.107)	-0.81 (0.342)	0.14 (0.498)	
95% CI [2]	-0.50, 0.08	-0.67, -0.25	-1.55, -0.07	-0.93, 1.22	
Difference (95% CI) in CFB [2]		-0.25 (-0.56, 0.06)		0.95 (0.12, 1.79)	
p-value [3]		0.113		0.029	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	53	103	10	6	
Mean (StdDev)	2.0 (1.29)	1.7 (1.29)	1.5 (1.27)	0.7 (0.52)	
Median	2.0	2.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 1	
C3D1 CFB					
n	51	103	10	6	
LS Mean (StdErr) [2]	-0.20 (0.165)	-0.69 (0.121)	-0.59 (0.457)	-1.35 (0.660)	
95% CI [2]	-0.53, 0.12	-0.93, -0.45	-1.58, 0.41	-2.79, 0.09	
Difference (95% CI) in CFB [2]		-0.49 (-0.84, -0.13)		-0.76 (-1.89, 0.36)	
p-value [3]		0.007		0.164	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	49	107	7	6	
Mean (StdDev)	1.9 (1.08)	1.6 (1.19)	1.4 (1.62)	1.0 (0.89)	
Median	2.0	2.0	1.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 2	
C4D1 CFB					
n	47	105	7	6	
LS Mean (StdErr) [2]	-0.26 (0.164)	-0.73 (0.119)	-0.63 (0.546)	-1.03 (0.895)	
95% CI [2]	-0.58, 0.07	-0.96, -0.49	-1.87, 0.60	-3.06, 0.99	
Difference (95% CI) in CFB [2]		-0.47 (-0.82, -0.13)		-0.40 (-2.16, 1.36)	
p-value [3]		0.007		0.619	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	50	104	9	5	
Mean (StdDev)	1.8 (1.21)	1.6 (1.24)	1.7 (1.32)	0.6 (0.55)	
Median	2.0	2.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 3	0, 1	
C5D1 CFB					
n	49	100	9	5	
LS Mean (StdErr) [2]	-0.43 (0.168)	-0.90 (0.124)	-0.45 (0.760)	-1.21 (1.168)	
95% CI [2]	-0.76, -0.10	-1.14, -0.65	-2.14, 1.25	-3.81, 1.39	
Difference (95% CI) in CFB [2]		-0.47 (-0.83, -0.11)		-0.76 (-2.89, 1.37)	
p-value [3]		0.011		0.445	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	50	105	8	6	
Mean (StdDev)	2.1 (1.23)	1.6 (1.36)	1.9 (1.13)	0.7 (0.82)	
Median	2.0	2.0	2.0	0.5	
Min, Max	0, 4	0, 4	0, 3	0, 2	
C6D1 CFB					
n	49	101	8	6	
LS Mean (StdErr) [2]	-0.09 (0.182)	-0.80 (0.133)	0.10 (0.540)	-0.28 (0.897)	
95% CI [2]	-0.45, 0.27	-1.06, -0.53	-1.11, 1.30	-2.28, 1.72	
Difference (95% CI) in CFB [2]		-0.71 (-1.10, -0.32)		-0.38 (-2.10, 1.34)	
p-value [3]		<0.001		0.634	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	48	105	10	6	
Mean (StdDev)	2.0 (1.40)	1.5 (1.36)	1.6 (1.26)	0.7 (0.52)	
Median	2.0	1.0	1.5	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 1	
C7D1 CFB					
n	47	101	10	6	
LS Mean (StdErr) [2]	-0.14 (0.181)	-0.75 (0.129)	-0.63 (0.461)	-1.80 (0.666)	
95% CI [2]	-0.50, 0.22	-1.00, -0.49	-1.63, 0.37	-3.25, -0.35	
Difference (95% CI) in CFB [2]		-0.61 (-0.99, -0.23)		-1.17 (-2.30, -0.04)	
Hedges'G (95% CI) in CFB		-0.47 (-0.83, -0.13)		-0.73 (-2.00, 0.30)	
p-value [3]		0.002		0.044	
					0.506

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	54	113	11	6	
Mean (StdDev)	2.0 (1.37)	2.2 (1.30)	1.5 (1.51)	2.0 (1.41)	
Median	2.0	2.0	1.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	54	113	11	6	
Mean (StdDev)	1.5 (1.22)	1.6 (1.29)	1.2 (1.17)	1.5 (1.05)	
Median	1.0	1.0	1.0	1.5	
Min, Max	0, 4	0, 4	0, 3	0, 3	
C2D1 CFB					
n	52	110	11	6	
LS Mean (StdErr) [2]	-0.39 (0.163)	-0.46 (0.121)	-0.67 (0.501)	-0.94 (0.730)	
95% CI [2]	-0.72, -0.07	-0.70, -0.22	-1.75, 0.41	-2.52, 0.63	
Difference (95% CI) in CFB [2]		-0.07 (-0.42, 0.28)		-0.27 (-1.50, 0.95)	
p-value [3]		0.706		0.639	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	53	103	10	6	
Mean (StdDev)	1.7 (1.31)	1.5 (1.30)	1.2 (1.14)	0.8 (0.98)	
Median	2.0	1.0	1.0	0.5	
Min, Max	0, 4	0, 4	0, 3	0, 2	
C3D1 CFB					
n	51	103	10	6	
LS Mean (StdErr) [2]	-0.37 (0.169)	-0.62 (0.124)	-0.43 (0.498)	-1.39 (0.720)	
95% CI [2]	-0.70, -0.03	-0.86, -0.37	-1.52, 0.65	-2.96, 0.18	
Difference (95% CI) in CFB [2]		-0.25 (-0.61, 0.11)		-0.96 (-2.19, 0.26)	
p-value [3]		0.170		0.113	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	49	107	7	6	
Mean (StdDev)	1.6 (1.15)	1.4 (1.27)	1.4 (1.27)	0.7 (0.82)	
Median	2.0	1.0	1.0	0.5	
Min, Max	0, 4	0, 4	0, 3	0, 2	
C4D1 CFB					
n	47	105	7	6	
LS Mean (StdErr) [2]	-0.47 (0.170)	-0.74 (0.123)	-0.53 (0.710)	-1.23 (1.165)	
95% CI [2]	-0.81, -0.14	-0.98, -0.50	-2.13, 1.08	-3.86, 1.41	
Difference (95% CI) in CFB [2]		-0.27 (-0.62, 0.09)		-0.70 (-2.99, 1.59)	
p-value [3]		0.139		0.506	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	50	104	9	5	
Mean (StdDev)	1.5 (1.28)	1.4 (1.23)	1.7 (1.50)	0.8 (1.10)	
Median	1.0	1.0	2.0	0.0	
Min, Max	0, 4	0, 4	0, 4	0, 2	
C5D1 CFB					
n	49	100	9	5	
LS Mean (StdErr) [2]	-0.44 (0.176)	-0.78 (0.130)	-0.16 (0.732)	-0.88 (1.124)	
95% CI [2]	-0.79, -0.09	-1.04, -0.52	-1.79, 1.47	-3.38, 1.62	
Difference (95% CI) in CFB [2]		-0.34 (-0.71, 0.04)		-0.72 (-2.77, 1.34)	
p-value [3]		0.078		0.454	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	50	105	8	6	
Mean (StdDev)	1.8 (1.29)	1.5 (1.35)	1.3 (1.04)	0.3 (0.82)	
Median	2.0	1.0	1.0	0.0	
Min, Max	0, 4	0, 4	0, 3	0, 2	
C6D1 CFB					
n	49	101	8	6	
LS Mean (StdErr) [2]	-0.24 (0.179)	-0.76 (0.131)	-0.93 (0.754)	-1.92 (1.252)	
95% CI [2]	-0.59, 0.11	-1.02, -0.50	-2.61, 0.75	-4.70, 0.87	
Difference (95% CI) in CFB [2]		-0.52 (-0.90, -0.14)		-0.99 (-3.39, 1.42)	
p-value [3]		0.008		0.382	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	48	105	10	6	
Mean (StdDev)	1.6 (1.36)	1.4 (1.37)	1.1 (1.10)	0.3 (0.52)	
Median	2.0	1.0	1.0	0.0	
Min, Max	0, 4	0, 4	0, 3	0, 1	
C7D1 CFB					
n	47	101	10	6	
LS Mean (StdErr) [2]	-0.17 (0.185)	-0.64 (0.132)	-1.02 (0.605)	-2.75 (0.875)	
95% CI [2]	-0.54, 0.19	-0.90, -0.38	-2.34, 0.30	-4.65, -0.84	
Difference (95% CI) in CFB [2]		-0.47 (-0.86, -0.08)		-1.73 (-3.21, -0.24)	
Hedges'G (95% CI) in CFB		-0.36 (-0.71, -0.01)		-0.82 (-2.11, 0.20)	
p-value [3]		0.019		0.027	
					0.152

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	54	113	11	6	
Mean (StdDev)	3.0 (0.95)	2.9 (1.03)	2.8 (0.75)	3.2 (0.41)	
Median	3.0	3.0	3.0	3.0	
Min, Max	0, 4	0, 4	2, 4	3, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	54	113	11	6	
Mean (StdDev)	2.5 (1.11)	2.5 (1.00)	2.5 (0.93)	3.0 (1.26)	
Median	3.0	2.0	2.0	3.5	
Min, Max	0, 4	0, 4	1, 4	1, 4	
C2D1 CFB					
n	52	110	11	6	
LS Mean (StdErr) [2]	-0.52 (0.144)	-0.46 (0.107)	-0.74 (0.464)	-0.92 (0.677)	
95% CI [2]	-0.80, -0.23	-0.67, -0.25	-1.74, 0.26	-2.38, 0.54	
Difference (95% CI) in CFB [2]		0.05 (-0.26, 0.36)		-0.18 (-1.32, 0.96)	
p-value [3]		0.736		0.735	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	53	103	10	6	
Mean (StdDev)	2.5 (1.10)	2.2 (1.13)	2.9 (0.74)	1.8 (1.17)	
Median	3.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	2, 4	0, 3	
C3D1 CFB					
n	51	103	10	6	
LS Mean (StdErr) [2]	-0.48 (0.152)	-0.58 (0.111)	0.04 (0.494)	-1.47 (0.714)	
95% CI [2]	-0.78, -0.18	-0.80, -0.36	-1.04, 1.11	-3.02, 0.09	
Difference (95% CI) in CFB [2]		-0.10 (-0.42, 0.23)		-1.50 (-2.72, -0.29)	
p-value [3]		0.552		0.019	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	49	107	7	6	
Mean (StdDev)	2.3 (1.26)	2.4 (1.21)	2.9 (0.69)	1.5 (0.84)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	2, 4	0, 2	
C4D1 CFB					
n	47	105	7	6	
LS Mean (StdErr) [2]	-0.72 (0.169)	-0.49 (0.122)	0.03 (0.482)	-1.37 (0.790)	
95% CI [2]	-1.05, -0.39	-0.73, -0.25	-1.06, 1.12	-3.15, 0.42	
Difference (95% CI) in CFB [2]		0.23 (-0.12, 0.58)		-1.40 (-2.95, 0.15)	
p-value [3]		0.195		0.072	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	51	104	9	5	
Mean (StdDev)	2.5 (1.06)	2.1 (1.27)	2.8 (0.83)	1.2 (1.30)	
Median	3.0	2.0	3.0	1.0	
Min, Max	0, 4	0, 4	2, 4	0, 3	
C5D1 CFB					
n	50	100	9	5	
LS Mean (StdErr) [2]	-0.54 (0.179)	-0.88 (0.132)	-0.50 (0.588)	-2.50 (0.903)	
95% CI [2]	-0.89, -0.18	-1.14, -0.62	-1.81, 0.81	-4.51, -0.49	
Difference (95% CI) in CFB [2]		-0.35 (-0.73, 0.04)		-2.00 (-3.65, -0.35)	
p-value [3]		0.076		0.022	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	50	105	8	6	
Mean (StdDev)	2.5 (1.25)	2.2 (1.23)	2.8 (0.89)	1.2 (0.75)	
Median	3.0	2.0	2.5	1.0	
Min, Max	0, 4	0, 4	2, 4	0, 2	
C6D1 CFB					
n	49	101	8	6	
LS Mean (StdErr) [2]	-0.32 (0.188)	-0.57 (0.138)	-0.42 (0.445)	-2.51 (0.738)	
95% CI [2]	-0.69, 0.05	-0.85, -0.30	-1.41, 0.57	-4.15, -0.86	
Difference (95% CI) in CFB [2]		-0.25 (-0.65, 0.15)		-2.08 (-3.50, -0.67)	
p-value [3]		0.217		0.008	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	48	105	10	6	
Mean (StdDev)	2.5 (1.17)	2.2 (1.21)	2.7 (0.82)	1.5 (0.84)	
Median	3.0	2.0	2.5	1.0	
Min, Max	0, 4	0, 4	2, 4	1, 3	
C7D1 CFB					
n	47	101	10	6	
LS Mean (StdErr) [2]	-0.42 (0.176)	-0.63 (0.126)	-0.46 (0.518)	-2.01 (0.748)	
95% CI [2]	-0.76, -0.07	-0.88, -0.38	-1.59, 0.67	-3.64, -0.38	
Difference (95% CI) in CFB [2]		-0.21 (-0.58, 0.16)		-1.55 (-2.82, -0.28)	
Hedges'G (95% CI) in CFB		-0.17 (-0.52, 0.18)		-0.86 (-2.17, 0.16)	
p-value [3]		0.260		0.021	
					0.026

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	54	113	11	6	
Mean (StdDev)	2.4 (1.47)	2.5 (1.21)	2.9 (1.38)	1.7 (1.37)	
Median	3.0	3.0	3.0	1.5	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	54	113	11	6	
Mean (StdDev)	2.2 (1.20)	2.0 (1.38)	2.2 (1.40)	1.7 (1.03)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 3	
C2D1 CFB					
n	52	110	11	6	
LS Mean (StdErr) [2]	-0.18 (0.166)	-0.51 (0.122)	-1.19 (0.483)	-0.19 (0.705)	
95% CI [2]	-0.50, 0.15	-0.75, -0.27	-2.23, -0.14	-1.71, 1.34	
Difference (95% CI) in CFB [2]		-0.33 (-0.69, 0.02)		1.00 (-0.18, 2.18)	
p-value [3]		0.064		0.091	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	53	103	10	6	
Mean (StdDev)	2.3 (1.21)	1.8 (1.28)	2.3 (1.25)	0.7 (0.82)	
Median	2.0	2.0	2.0	0.5	
Min, Max	0, 4	0, 4	0, 4	0, 2	
C3D1 CFB					
n	51	103	10	6	
LS Mean (StdErr) [2]	-0.18 (0.183)	-0.67 (0.134)	-1.11 (0.612)	-1.60 (0.885)	
95% CI [2]	-0.54, 0.18	-0.93, -0.40	-2.44, 0.23	-3.53, 0.33	
Difference (95% CI) in CFB [2]		-0.49 (-0.88, -0.09)		-0.49 (-2.00, 1.02)	
p-value [3]		0.016		0.492	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	49	107	7	6	
Mean (StdDev)	2.0 (1.29)	1.9 (1.42)	2.1 (1.46)	1.2 (1.17)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 3	
C4D1 CFB					
n	47	105	7	6	
LS Mean (StdErr) [2]	-0.39 (0.181)	-0.64 (0.131)	-1.25 (0.405)	-1.25 (0.665)	
95% CI [2]	-0.74, -0.03	-0.90, -0.38	-2.17, -0.33	-2.75, 0.25	
Difference (95% CI) in CFB [2]		-0.26 (-0.64, 0.12)		0.00 (-1.31, 1.31)	
p-value [3]		0.183		>0.999	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	51	104	9	5	
Mean (StdDev)	1.9 (1.49)	1.8 (1.46)	2.4 (1.33)	0.6 (0.89)	
Median	2.0	2.0	3.0	0.0	
Min, Max	0, 4	0, 4	0, 4	0, 2	
C5D1 CFB					
n	50	100	9	5	
LS Mean (StdErr) [2]	-0.43 (0.185)	-0.73 (0.137)	-1.02 (0.365)	-1.72 (0.561)	
95% CI [2]	-0.80, -0.07	-1.00, -0.45	-1.84, -0.21	-2.97, -0.47	
Difference (95% CI) in CFB [2]		-0.29 (-0.69, 0.10)		-0.70 (-1.72, 0.33)	
p-value [3]		0.143		0.161	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	50	105	8	6	
Mean (StdDev)	2.1 (1.29)	1.7 (1.39)	2.9 (1.25)	0.7 (0.82)	
Median	2.0	2.0	3.0	0.5	
Min, Max	0, 4	0, 4	1, 4	0, 2	
C6D1 CFB					
n	49	101	8	6	
LS Mean (StdErr) [2]	-0.20 (0.188)	-0.82 (0.138)	-0.35 (0.520)	-1.51 (0.864)	
95% CI [2]	-0.58, 0.17	-1.09, -0.54	-1.50, 0.81	-3.44, 0.41	
Difference (95% CI) in CFB [2]		-0.61 (-1.01, -0.21)		-1.17 (-2.83, 0.49)	
p-value [3]		0.003		0.148	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	48	105	10	6	
Mean (StdDev)	2.0 (1.38)	1.6 (1.41)	2.5 (1.65)	0.8 (1.33)	
Median	2.0	1.0	3.0	0.0	
Min, Max	0, 4	0, 4	0, 4	0, 3	
C7D1 CFB					
n	47	101	10	6	
LS Mean (StdErr) [2]	-0.33 (0.194)	-0.78 (0.139)	-1.51 (0.596)	-2.37 (0.862)	
95% CI [2]	-0.71, 0.05	-1.05, -0.51	-2.81, -0.21	-4.25, -0.49	
Difference (95% CI) in CFB [2]		-0.45 (-0.86, -0.04)		-0.86 (-2.33, 0.60)	
Hedges'G (95% CI) in CFB		-0.33 (-0.68, 0.02)		-0.41 (-1.61, 0.63)	
p-value [3]		0.032		0.224	
					0.899

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	54	113	11	6	
Mean (StdDev)	2.8 (1.11)	3.0 (0.98)	2.5 (1.29)	2.7 (0.52)	
Median	3.0	3.0	3.0	3.0	
Min, Max	0, 4	0, 4	0, 4	2, 3	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	54	113	11	6	
Mean (StdDev)	2.3 (1.11)	2.3 (1.26)	1.8 (1.17)	2.0 (0.63)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	1, 3	
C2D1 CFB					
n	52	110	11	6	
LS Mean (StdErr) [2]	-0.56 (0.160)	-0.73 (0.118)	-0.82 (0.340)	-0.68 (0.496)	
95% CI [2]	-0.87, -0.24	-0.97, -0.50	-1.56, -0.09	-1.76, 0.39	
Difference (95% CI) in CFB [2]		-0.18 (-0.52, 0.16)		0.14 (-0.70, 0.97)	
p-value [3]		0.307		0.729	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	53	103	10	6	
Mean (StdDev)	2.5 (1.17)	2.1 (1.24)	1.8 (1.32)	1.8 (0.75)	
Median	3.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	1, 3	
C3D1 CFB					
n	51	103	10	6	
LS Mean (StdErr) [2]	-0.37 (0.173)	-0.93 (0.127)	-0.71 (0.591)	-0.78 (0.855)	
95% CI [2]	-0.71, -0.03	-1.18, -0.68	-2.00, 0.58	-2.64, 1.08	
Difference (95% CI) in CFB [2]		-0.56 (-0.93, -0.19)		-0.07 (-1.52, 1.38)	
p-value [3]		0.003		0.916	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	49	107	7	6	
Mean (StdDev)	2.5 (1.19)	2.1 (1.21)	2.4 (1.13)	0.8 (1.17)	
Median	2.0	2.0	2.0	0.5	
Min, Max	0, 4	0, 4	1, 4	0, 3	
C4D1 CFB					
n	47	105	7	6	
LS Mean (StdErr) [2]	-0.44 (0.172)	-0.93 (0.124)	-0.41 (0.596)	-1.51 (0.978)	
95% CI [2]	-0.78, -0.10	-1.18, -0.68	-1.76, 0.94	-3.72, 0.70	
Difference (95% CI) in CFB [2]		-0.49 (-0.85, -0.13)		-1.10 (-3.02, 0.82)	
p-value [3]		0.008		0.227	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	51	103	9	5	
Mean (StdDev)	2.3 (1.20)	2.1 (1.18)	2.6 (1.13)	0.8 (1.10)	
Median	2.0	2.0	3.0	0.0	
Min, Max	0, 4	0, 4	1, 4	0, 2	
C5D1 CFB					
n	50	99	9	5	
LS Mean (StdErr) [2]	-0.59 (0.164)	-1.01 (0.121)	-0.22 (0.690)	-1.17 (1.060)	
95% CI [2]	-0.91, -0.27	-1.25, -0.77	-1.76, 1.32	-3.54, 1.19	
Difference (95% CI) in CFB [2]		-0.42 (-0.78, -0.07)		-0.96 (-2.89, 0.98)	
p-value [3]		0.018		0.297	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	50	105	8	6	
Mean (StdDev)	2.5 (1.20)	1.9 (1.33)	2.5 (0.93)	1.5 (0.84)	
Median	2.5	2.0	2.5	1.0	
Min, Max	0, 4	0, 4	1, 4	1, 3	
C6D1 CFB					
n	49	101	8	6	
LS Mean (StdErr) [2]	-0.39 (0.184)	-1.13 (0.135)	-0.37 (0.501)	-1.15 (0.831)	
95% CI [2]	-0.75, -0.02	-1.39, -0.86	-1.49, 0.74	-3.00, 0.70	
Difference (95% CI) in CFB [2]		-0.74 (-1.13, -0.35)		-0.77 (-2.37, 0.82)	
p-value [3]		<0.001		0.305	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	48	105	10	6	
Mean (StdDev)	2.3 (1.30)	2.0 (1.33)	2.0 (1.49)	0.8 (0.75)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 2	
C7D1 CFB					
n	47	101	10	6	
LS Mean (StdErr) [2]	-0.42 (0.184)	-0.93 (0.131)	-0.50 (0.536)	-1.50 (0.775)	
95% CI [2]	-0.78, -0.06	-1.19, -0.67	-1.67, 0.67	-3.19, 0.19	
Difference (95% CI) in CFB [2]		-0.51 (-0.90, -0.12)		-1.00 (-2.32, 0.32)	
Hedges'G (95% CI) in CFB		-0.39 (-0.75, -0.05)		-0.53 (-1.76, 0.50)	
p-value [3]		0.010		0.124	
					0.180

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	54	113	11	6	
Mean (StdDev)	3.1 (0.92)	3.1 (0.95)	3.0 (1.00)	3.3 (0.82)	
Median	3.0	3.0	3.0	3.5	
Min, Max	0, 4	0, 4	1, 4	2, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-age-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	54	113	11	6	
Mean (StdDev)	2.6 (0.94)	2.3 (1.08)	2.7 (1.27)	2.3 (1.21)	
Median	3.0	2.0	3.0	3.0	
Min, Max	1, 4	0, 4	0, 4	0, 3	
C2D1 CFB					
n	52	110	11	6	
LS Mean (StdErr) [2]	-0.47 (0.144)	-0.76 (0.106)	-0.63 (0.345)	-1.54 (0.503)	
95% CI [2]	-0.75, -0.18	-0.97, -0.55	-1.38, 0.11	-2.63, -0.45	
Difference (95% CI) in CFB [2]		-0.29 (-0.60, 0.01)		-0.91 (-1.75, -0.06)	
p-value [3]		0.061		0.037	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	53	103	10	6	
Mean (StdDev)	2.5 (1.10)	2.2 (1.17)	2.6 (1.07)	1.3 (1.03)	
Median	3.0	2.0	3.0	1.0	
Min, Max	0, 4	0, 4	1, 4	0, 3	
C3D1 CFB					
n	51	103	10	6	
LS Mean (StdErr) [2]	-0.64 (0.164)	-0.96 (0.120)	-0.53 (0.407)	-2.08 (0.589)	
95% CI [2]	-0.97, -0.32	-1.20, -0.72	-1.42, 0.36	-3.36, -0.79	
Difference (95% CI) in CFB [2]		-0.32 (-0.67, 0.04)		-1.54 (-2.54, -0.54)	
p-value [3]		0.078		0.006	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-age-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	49	107	7	6	
Mean (StdDev)	2.4 (1.13)	2.2 (1.14)	2.9 (1.21)	1.3 (0.82)	
Median	2.0	2.0	3.0	1.5	
Min, Max	0, 4	0, 4	1, 4	0, 2	
C4D1 CFB					
n	47	105	7	6	
LS Mean (StdErr) [2]	-0.80 (0.159)	-1.08 (0.115)	-0.36 (0.445)	-2.06 (0.729)	
95% CI [2]	-1.12, -0.49	-1.30, -0.85	-1.36, 0.65	-3.71, -0.41	
Difference (95% CI) in CFB [2]		-0.27 (-0.61, 0.06)		-1.70 (-3.13, -0.27)	
p-value [3]		0.106		0.025	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-age-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	51	104	9	5	
Mean (StdDev)	2.3 (1.31)	2.2 (1.19)	2.9 (1.05)	1.4 (0.89)	
Median	3.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 2	
C5D1 CFB					
n	50	100	9	5	
LS Mean (StdErr) [2]	-0.67 (0.176)	-0.97 (0.130)	-0.70 (0.525)	-1.96 (0.806)	
95% CI [2]	-1.01, -0.32	-1.23, -0.72	-1.87, 0.47	-3.75, -0.16	
Difference (95% CI) in CFB [2]		-0.31 (-0.68, 0.07)		-1.26 (-2.73, 0.21)	
p-value [3]		0.108		0.085	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	50	105	8	6	
Mean (StdDev)	2.5 (1.16)	2.1 (1.28)	3.0 (1.07)	1.0 (0.89)	
Median	3.0	2.0	3.0	1.0	
Min, Max	0, 4	0, 4	1, 4	0, 2	
C6D1 CFB					
n	49	101	8	6	
LS Mean (StdErr) [2]	-0.57 (0.184)	-1.08 (0.135)	-0.71 (0.388)	-2.75 (0.644)	
95% CI [2]	-0.93, -0.20	-1.35, -0.82	-1.58, 0.15	-4.19, -1.32	
Difference (95% CI) in CFB [2]		-0.52 (-0.91, -0.12)		-2.04 (-3.28, -0.81)	
p-value [3]		0.010		0.004	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	48	105	10	6	
Mean (StdDev)	2.4 (1.33)	2.0 (1.27)	2.6 (1.35)	0.8 (0.75)	
Median	3.0	2.0	3.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 2	
C7D1 CFB					
n	47	101	10	6	
LS Mean (StdErr) [2]	-0.59 (0.189)	-1.01 (0.135)	-0.99 (0.487)	-3.17 (0.705)	
95% CI [2]	-0.97, -0.22	-1.28, -0.74	-2.05, 0.07	-4.71, -1.63	
Difference (95% CI) in CFB [2]		-0.41 (-0.81, -0.02)		-2.18 (-3.38, -0.99)	
Hedges'G (95% CI) in CFB		-0.31 (-0.66, 0.04)		-1.28 (-2.73, -0.27)	
p-value [3]		0.042		0.002	
					0.007

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-age-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	54	113	11	6	
Mean (StdDev)	2.2 (1.38)	1.8 (1.51)	2.6 (1.75)	2.5 (0.55)	
Median	2.5	2.0	4.0	2.5	
Min, Max	0, 4	0, 4	0, 4	2, 3	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	54	113	11	6	
Mean (StdDev)	1.9 (1.41)	1.5 (1.44)	2.5 (1.44)	1.3 (1.03)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 3	
C2D1 CFB					
n	52	110	11	6	
LS Mean (StdErr) [2]	-0.06 (0.184)	-0.12 (0.136)	0.26 (0.415)	-0.92 (0.605)	
95% CI [2]	-0.43, 0.30	-0.39, 0.15	-0.63, 1.16	-2.23, 0.39	
Difference (95% CI) in CFB [2]		-0.06 (-0.45, 0.33)		-1.18 (-2.20, -0.17)	
p-value [3]		0.766		0.026	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	53	103	10	6	
Mean (StdDev)	2.0 (1.35)	1.5 (1.43)	2.2 (1.62)	0.3 (0.82)	
Median	2.0	1.0	1.5	0.0	
Min, Max	0, 4	0, 4	0, 4	0, 2	
C3D1 CFB					
n	51	103	10	6	
LS Mean (StdErr) [2]	-0.06 (0.199)	-0.26 (0.146)	-0.27 (0.481)	-2.43 (0.695)	
95% CI [2]	-0.45, 0.33	-0.55, 0.03	-1.32, 0.77	-3.95, -0.92	
Difference (95% CI) in CFB [2]		-0.20 (-0.63, 0.22)		-2.16 (-3.34, -0.97)	
p-value [3]		0.351		0.002	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	49	107	7	6	
Mean (StdDev)	1.9 (1.22)	1.6 (1.43)	2.0 (1.73)	0.8 (1.33)	
Median	2.0	1.0	2.0	0.0	
Min, Max	0, 4	0, 4	0, 4	0, 3	
C4D1 CFB					
n	47	105	7	6	
LS Mean (StdErr) [2]	-0.23 (0.194)	-0.18 (0.140)	-0.70 (0.459)	-2.30 (0.752)	
95% CI [2]	-0.61, 0.16	-0.45, 0.10	-1.74, 0.34	-4.00, -0.60	
Difference (95% CI) in CFB [2]		0.05 (-0.36, 0.45)		-1.60 (-3.08, -0.12)	
p-value [3]		0.815		0.037	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	51	104	9	5	
Mean (StdDev)	1.8 (1.37)	1.5 (1.40)	2.0 (1.32)	0.0 (0.00)	
Median	2.0	1.0	1.0	0.0	
Min, Max	0, 4	0, 4	1, 4	0, 0	
C5D1 CFB					
n	50	100	9	5	
LS Mean (StdErr) [2]	-0.25 (0.206)	-0.25 (0.153)	-0.26 (0.595)	-2.61 (0.913)	
95% CI [2]	-0.66, 0.15	-0.55, 0.05	-1.59, 1.06	-4.64, -0.57	
Difference (95% CI) in CFB [2]		0.00 (-0.44, 0.45)		-2.35 (-4.02, -0.68)	
p-value [3]		0.984		0.011	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	50	105	8	6	
Mean (StdDev)	1.8 (1.46)	1.4 (1.37)	2.4 (1.41)	0.5 (0.84)	
Median	2.0	1.0	2.5	0.0	
Min, Max	0, 4	0, 4	0, 4	0, 2	
C6D1 CFB					
n	49	101	8	6	
LS Mean (StdErr) [2]	-0.28 (0.218)	-0.35 (0.159)	-0.58 (0.505)	-2.49 (0.839)	
95% CI [2]	-0.71, 0.15	-0.66, -0.03	-1.70, 0.55	-4.36, -0.62	
Difference (95% CI) in CFB [2]		-0.06 (-0.53, 0.40)		-1.92 (-3.53, -0.30)	
p-value [3]		0.791		0.024	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	48	105	10	6	
Mean (StdDev)	1.9 (1.53)	1.3 (1.37)	2.4 (1.26)	0.3 (0.52)	
Median	2.0	1.0	2.5	0.0	
Min, Max	0, 4	0, 4	0, 4	0, 1	
C7D1 CFB					
n	47	101	10	6	
LS Mean (StdErr) [2]	-0.02 (0.220)	-0.25 (0.157)	-0.12 (0.519)	-2.39 (0.751)	
95% CI [2]	-0.45, 0.42	-0.56, 0.06	-1.26, 1.01	-4.02, -0.75	
Difference (95% CI) in CFB [2]		-0.24 (-0.70, 0.23)		-2.26 (-3.54, -0.99)	
Hedges'G (95% CI) in CFB		-0.15 (-0.50, 0.19)		-1.25 (-2.68, -0.24)	
p-value [3]		0.313		0.002	
					0.028

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-age-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	54	113	11	6	
Mean (StdDev)	1.8 (1.25)	1.8 (1.31)	1.5 (1.21)	2.2 (1.47)	
Median	2.0	2.0	1.0	2.5	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-age-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	54	113	11	6	
Mean (StdDev)	1.6 (1.06)	1.4 (1.27)	1.3 (1.27)	1.3 (1.21)	
Median	1.0	1.0	1.0	1.5	
Min, Max	0, 4	0, 4	0, 3	0, 3	
C2D1 CFB					
n	52	110	11	6	
LS Mean (StdErr) [2]	-0.30 (0.136)	-0.41 (0.101)	-0.63 (0.255)	-1.63 (0.372)	
95% CI [2]	-0.57, -0.03	-0.61, -0.21	-1.18, -0.07	-2.43, -0.82	
Difference (95% CI) in CFB [2]		-0.11 (-0.40, 0.18)		-1.00 (-1.63, -0.37)	
p-value [3]		0.448		0.004	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	53	103	10	6	
Mean (StdDev)	1.6 (1.17)	1.2 (1.23)	1.3 (1.16)	0.5 (0.55)	
Median	1.0	1.0	1.0	0.5	
Min, Max	0, 4	0, 4	0, 4	0, 1	
C3D1 CFB					
n	51	103	10	6	
LS Mean (StdErr) [2]	-0.27 (0.175)	-0.62 (0.128)	-1.00 (0.486)	-2.96 (0.703)	
95% CI [2]	-0.62, 0.08	-0.87, -0.37	-2.06, 0.06	-4.49, -1.43	
Difference (95% CI) in CFB [2]		-0.35 (-0.72, 0.03)		-1.95 (-3.15, -0.76)	
p-value [3]		0.068		0.004	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	49	107	7	6	
Mean (StdDev)	1.5 (1.12)	1.1 (1.21)	2.1 (1.35)	0.8 (0.98)	
Median	1.0	1.0	2.0	0.5	
Min, Max	0, 4	0, 4	1, 4	0, 2	
C4D1 CFB					
n	47	105	7	6	
LS Mean (StdErr) [2]	-0.37 (0.178)	-0.70 (0.129)	-0.48 (0.708)	-2.68 (1.162)	
95% CI [2]	-0.73, -0.02	-0.96, -0.45	-2.09, 1.12	-5.31, -0.05	
Difference (95% CI) in CFB [2]		-0.33 (-0.70, 0.05)		-2.20 (-4.48, 0.08)	
p-value [3]		0.085		0.057	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	51	104	9	5	
Mean (StdDev)	1.5 (1.14)	1.1 (1.23)	1.8 (1.20)	0.6 (0.89)	
Median	1.0	1.0	2.0	0.0	
Min, Max	0, 4	0, 4	0, 4	0, 2	
C5D1 CFB					
n	50	100	9	5	
LS Mean (StdErr) [2]	-0.46 (0.165)	-0.78 (0.122)	-0.72 (0.658)	-2.67 (1.011)	
95% CI [2]	-0.79, -0.13	-1.02, -0.54	-2.18, 0.75	-4.93, -0.42	
Difference (95% CI) in CFB [2]		-0.32 (-0.67, 0.04)		-1.96 (-3.80, -0.11)	
p-value [3]		0.078		0.040	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	50	105	8	6	
Mean (StdDev)	1.5 (1.16)	1.1 (1.21)	1.9 (1.25)	0.7 (0.82)	
Median	1.0	1.0	2.0	0.5	
Min, Max	0, 4	0, 4	0, 4	0, 2	
C6D1 CFB					
n	49	101	8	6	
LS Mean (StdErr) [2]	-0.39 (0.168)	-0.68 (0.123)	-0.25 (0.556)	-2.70 (0.923)	
95% CI [2]	-0.72, -0.05	-0.92, -0.44	-1.49, 0.99	-4.76, -0.65	
Difference (95% CI) in CFB [2]		-0.29 (-0.65, 0.07)		-2.45 (-4.22, -0.68)	
p-value [3]		0.109		0.012	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	48	105	10	6	
Mean (StdDev)	1.4 (1.12)	1.0 (1.19)	1.2 (1.14)	0.8 (0.75)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 3	0, 2	
C7D1 CFB					
n	47	101	10	6	
LS Mean (StdErr) [2]	-0.40 (0.174)	-0.62 (0.124)	-0.61 (0.375)	-2.01 (0.542)	
95% CI [2]	-0.74, -0.05	-0.87, -0.38	-1.43, 0.20	-3.19, -0.83	
Difference (95% CI) in CFB [2]		-0.22 (-0.59, 0.14)		-1.40 (-2.32, -0.48)	
Hedges'G (95% CI) in CFB		-0.18 (-0.53, 0.17)		-1.07 (-2.44, -0.06)	
p-value [3]		0.230		0.006	
					0.140

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-age-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	54	113	11	6	
Mean (StdDev)	1.3 (1.32)	1.5 (1.46)	0.9 (1.04)	1.7 (1.86)	
Median	1.0	1.0	1.0	1.5	
Min, Max	0, 4	0, 4	0, 3	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-age-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	54	113	11	6	
Mean (StdDev)	1.3 (1.40)	1.2 (1.36)	0.8 (0.98)	1.5 (1.64)	
Median	1.0	1.0	0.0	1.0	
Min, Max	0, 4	0, 4	0, 2	0, 4	
C2D1 CFB					
n	52	110	11	6	
LS Mean (StdErr) [2]	0.07 (0.159)	-0.11 (0.118)	0.05 (0.431)	0.32 (0.628)	
95% CI [2]	-0.25, 0.38	-0.34, 0.12	-0.89, 0.98	-1.04, 1.68	
Difference (95% CI) in CFB [2]		-0.18 (-0.52, 0.16)		0.27 (-0.78, 1.33)	
p-value [3]		0.303		0.586	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	53	103	10	6	
Mean (StdDev)	1.1 (1.15)	1.0 (1.25)	0.8 (1.48)	1.0 (1.26)	
Median	1.0	0.0	0.0	0.5	
Min, Max	0, 4	0, 4	0, 4	0, 3	
C3D1 CFB					
n	51	103	10	6	
LS Mean (StdErr) [2]	-0.09 (0.182)	-0.32 (0.133)	0.41 (0.381)	-0.27 (0.551)	
95% CI [2]	-0.45, 0.27	-0.58, -0.05	-0.43, 1.24	-1.47, 0.93	
Difference (95% CI) in CFB [2]		-0.22 (-0.61, 0.17)		-0.67 (-1.61, 0.26)	
p-value [3]		0.263		0.144	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	49	107	7	6	
Mean (StdDev)	1.3 (1.26)	1.1 (1.26)	2.0 (1.29)	0.7 (0.82)	
Median	1.0	1.0	1.0	0.5	
Min, Max	0, 4	0, 4	1, 4	0, 2	
C4D1 CFB					
n	47	105	7	6	
LS Mean (StdErr) [2]	-0.16 (0.186)	-0.46 (0.134)	0.95 (0.612)	-1.45 (1.004)	
95% CI [2]	-0.53, 0.21	-0.72, -0.19	-0.43, 2.33	-3.72, 0.82	
Difference (95% CI) in CFB [2]		-0.30 (-0.69, 0.09)		-2.40 (-4.37, -0.43)	
p-value [3]		0.130		0.022	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	51	104	9	5	
Mean (StdDev)	1.2 (1.31)	1.0 (1.25)	1.2 (0.97)	0.6 (0.89)	
Median	1.0	0.0	1.0	0.0	
Min, Max	0, 4	0, 4	0, 3	0, 2	
C5D1 CFB					
n	50	100	9	5	
LS Mean (StdErr) [2]	-0.12 (0.175)	-0.54 (0.129)	0.16 (0.436)	-1.12 (0.669)	
95% CI [2]	-0.47, 0.22	-0.79, -0.28	-0.81, 1.13	-2.61, 0.37	
Difference (95% CI) in CFB [2]		-0.41 (-0.79, -0.04)		-1.28 (-2.50, -0.06)	
p-value [3]		0.030		0.041	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	50	105	8	6	
Mean (StdDev)	1.2 (1.25)	1.0 (1.22)	1.3 (1.28)	0.5 (0.84)	
Median	1.0	0.0	1.0	0.0	
Min, Max	0, 4	0, 4	0, 3	0, 2	
C6D1 CFB					
n	49	101	8	6	
LS Mean (StdErr) [2]	-0.12 (0.178)	-0.52 (0.131)	0.62 (0.591)	-1.06 (0.981)	
95% CI [2]	-0.47, 0.24	-0.78, -0.26	-0.70, 1.94	-3.24, 1.13	
Difference (95% CI) in CFB [2]		-0.40 (-0.79, -0.02)		-1.68 (-3.56, 0.21)	
p-value [3]		0.038		0.076	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	48	105	10	6	
Mean (StdDev)	1.2 (1.19)	0.9 (1.27)	0.8 (1.23)	0.7 (1.03)	
Median	1.0	0.0	0.0	0.0	
Min, Max	0, 4	0, 4	0, 3	0, 2	
C7D1 CFB					
n	47	101	10	6	
LS Mean (StdErr) [2]	-0.00 (0.180)	-0.39 (0.128)	0.42 (0.510)	-0.52 (0.737)	
95% CI [2]	-0.36, 0.35	-0.65, -0.14	-0.69, 1.54	-2.13, 1.08	
Difference (95% CI) in CFB [2]		-0.39 (-0.77, -0.01)		-0.95 (-2.20, 0.31)	
Hedges'G (95% CI) in CFB		-0.31 (-0.66, 0.04)		-0.53 (-1.75, 0.51)	
p-value [3]		0.043		0.125	
					0.435

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	54	113	11	6	
Mean (StdDev)	1.9 (1.12)	2.0 (1.28)	2.3 (1.10)	1.8 (1.60)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	54	113	11	6	
Mean (StdDev)	1.5 (1.28)	1.5 (1.28)	1.8 (1.08)	1.3 (1.03)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 3	
C2D1 CFB					
n	52	110	11	6	
LS Mean (StdErr) [2]	-0.48 (0.166)	-0.58 (0.123)	-0.74 (0.460)	-0.96 (0.671)	
95% CI [2]	-0.81, -0.15	-0.83, -0.34	-1.73, 0.26	-2.41, 0.49	
Difference (95% CI) in CFB [2]		-0.11 (-0.46, 0.25)		-0.23 (-1.35, 0.90)	
p-value [3]		0.552		0.670	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	53	103	10	6	
Mean (StdDev)	1.5 (1.07)	1.4 (1.13)	1.7 (1.42)	0.5 (0.84)	
Median	2.0	1.0	1.5	0.0	
Min, Max	0, 3	0, 4	0, 4	0, 2	
C3D1 CFB					
n	51	103	10	6	
LS Mean (StdErr) [2]	-0.38 (0.161)	-0.59 (0.118)	-0.72 (0.479)	-1.61 (0.692)	
95% CI [2]	-0.70, -0.07	-0.82, -0.35	-1.76, 0.32	-3.12, -0.10	
Difference (95% CI) in CFB [2]		-0.20 (-0.55, 0.14)		-0.89 (-2.07, 0.29)	
p-value [3]		0.250		0.126	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	49	107	7	6	
Mean (StdDev)	1.4 (1.19)	1.4 (1.22)	2.4 (1.40)	0.5 (0.84)	
Median	1.0	1.0	3.0	0.0	
Min, Max	0, 4	0, 4	1, 4	0, 2	
C4D1 CFB					
n	47	105	7	6	
LS Mean (StdErr) [2]	-0.48 (0.186)	-0.67 (0.134)	-0.16 (0.596)	-1.26 (0.978)	
95% CI [2]	-0.85, -0.11	-0.93, -0.40	-1.51, 1.19	-3.47, 0.95	
Difference (95% CI) in CFB [2]		-0.19 (-0.57, 0.20)		-1.10 (-3.02, 0.82)	
p-value [3]		0.344		0.227	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	51	104	9	5	
Mean (StdDev)	1.4 (1.28)	1.2 (1.19)	1.7 (1.50)	0.0 (0.00)	
Median	1.0	1.0	2.0	0.0	
Min, Max	0, 4	0, 4	0, 4	0, 0	
C5D1 CFB					
n	50	100	9	5	
LS Mean (StdErr) [2]	-0.36 (0.176)	-0.77 (0.130)	-1.18 (0.639)	-2.60 (0.981)	
95% CI [2]	-0.71, -0.01	-1.02, -0.51	-2.61, 0.24	-4.78, -0.41	
Difference (95% CI) in CFB [2]		-0.41 (-0.78, -0.03)		-1.41 (-3.21, 0.38)	
p-value [3]		0.034		0.109	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	50	105	8	6	
Mean (StdDev)	1.6 (1.30)	1.1 (1.14)	1.6 (1.30)	0.2 (0.41)	
Median	2.0	1.0	1.0	0.0	
Min, Max	0, 4	0, 4	0, 4	0, 1	
C6D1 CFB					
n	49	101	8	6	
LS Mean (StdErr) [2]	-0.28 (0.185)	-1.03 (0.135)	-0.75 (0.652)	-2.30 (1.082)	
95% CI [2]	-0.65, 0.08	-1.30, -0.77	-2.20, 0.71	-4.71, 0.11	
Difference (95% CI) in CFB [2]		-0.75 (-1.15, -0.36)		-1.55 (-3.63, 0.53)	
p-value [3]		<0.001		0.128	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-age-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	48	105	10	6	
Mean (StdDev)	1.6 (1.35)	1.2 (1.26)	1.6 (1.43)	0.3 (0.52)	
Median	2.0	1.0	1.5	0.0	
Min, Max	0, 4	0, 4	0, 4	0, 1	
C7D1 CFB					
n	47	101	10	6	
LS Mean (StdErr) [2]	-0.19 (0.213)	-0.72 (0.152)	-0.85 (0.643)	-2.00 (0.929)	
95% CI [2]	-0.61, 0.23	-1.02, -0.42	-2.25, 0.55	-4.02, 0.03	
Difference (95% CI) in CFB [2]		-0.53 (-0.98, -0.08)		-1.15 (-2.73, 0.43)	
Hedges'G (95% CI) in CFB		-0.35 (-0.71, -0.00)		-0.51 (-1.73, 0.53)	
p-value [3]		0.021		0.139	
					0.702

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-age-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	54	113	11	6	
Mean (StdDev)	2.3 (1.03)	2.3 (1.21)	2.7 (0.79)	2.5 (1.05)	
Median	2.0	2.0	3.0	2.5	
Min, Max	0, 4	0, 4	1, 4	1, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-age-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	54	113	11	6	
Mean (StdDev)	1.7 (1.10)	1.7 (1.31)	1.9 (1.30)	1.7 (1.03)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 3	
C2D1 CFB					
n	52	110	11	6	
LS Mean (StdErr) [2]	-0.39 (0.162)	-0.58 (0.120)	-0.98 (0.544)	-1.30 (0.793)	
95% CI [2]	-0.71, -0.07	-0.82, -0.34	-2.15, 0.19	-3.01, 0.41	
Difference (95% CI) in CFB [2]		-0.19 (-0.54, 0.16)		-0.32 (-1.65, 1.01)	
p-value [3]		0.276		0.615	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-age-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	53	103	10	6	
Mean (StdDev)	1.8 (1.13)	1.5 (1.14)	2.0 (1.05)	1.0 (0.89)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	1, 4	0, 2	
C3D1 CFB					
n	51	103	10	6	
LS Mean (StdErr) [2]	-0.41 (0.173)	-0.82 (0.127)	-0.75 (0.552)	-1.31 (0.798)	
95% CI [2]	-0.75, -0.06	-1.07, -0.57	-1.95, 0.46	-3.05, 0.42	
Difference (95% CI) in CFB [2]		-0.41 (-0.79, -0.04)		-0.57 (-1.93, 0.79)	
p-value [3]		0.029		0.379	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-age-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	49	106	7	6	
Mean (StdDev)	1.7 (1.13)	1.5 (1.27)	2.4 (0.98)	1.0 (1.10)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	1, 4	0, 2	
C4D1 CFB					
n	47	104	7	6	
LS Mean (StdErr) [2]	-0.62 (0.184)	-0.94 (0.133)	-0.98 (0.662)	-2.28 (1.087)	
95% CI [2]	-0.98, -0.26	-1.20, -0.67	-2.47, 0.52	-4.73, 0.18	
Difference (95% CI) in CFB [2]		-0.32 (-0.70, 0.07)		-1.30 (-3.43, 0.83)	
p-value [3]		0.107		0.201	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	51	104	9	5	
Mean (StdDev)	1.5 (1.27)	1.4 (1.24)	2.3 (1.50)	0.6 (0.89)	
Median	1.0	1.0	3.0	0.0	
Min, Max	0, 4	0, 4	0, 4	0, 2	
C5D1 CFB					
n	50	100	9	5	
LS Mean (StdErr) [2]	-0.74 (0.188)	-0.99 (0.139)	-0.55 (0.788)	-1.79 (1.210)	
95% CI [2]	-1.12, -0.37	-1.26, -0.71	-2.31, 1.20	-4.49, 0.90	
Difference (95% CI) in CFB [2]		-0.24 (-0.64, 0.16)		-1.24 (-3.45, 0.97)	
p-value [3]		0.238		0.240	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-age-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	50	105	8	6	
Mean (StdDev)	1.7 (1.22)	1.4 (1.27)	2.0 (1.41)	0.5 (0.55)	
Median	2.0	1.0	2.0	0.5	
Min, Max	0, 4	0, 4	0, 4	0, 1	
C6D1 CFB					
n	49	101	8	6	
LS Mean (StdErr) [2]	-0.57 (0.194)	-1.01 (0.142)	-1.62 (0.343)	-3.94 (0.570)	
95% CI [2]	-0.95, -0.18	-1.29, -0.73	-2.38, -0.85	-5.21, -2.67	
Difference (95% CI) in CFB [2]		-0.44 (-0.85, -0.02)		-2.32 (-3.42, -1.23)	
p-value [3]		0.039		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-age-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	48	105	10	6	
Mean (StdDev)	1.4 (1.20)	1.4 (1.28)	2.4 (1.07)	0.7 (0.52)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	1, 4	0, 1	
C7D1 CFB					
n	47	101	10	6	
LS Mean (StdErr) [2]	-0.67 (0.204)	-0.81 (0.146)	-0.60 (0.391)	-2.18 (0.565)	
95% CI [2]	-1.08, -0.27	-1.10, -0.52	-1.45, 0.25	-3.41, -0.95	
Difference (95% CI) in CFB [2]		-0.14 (-0.57, 0.29)		-1.58 (-2.54, -0.62)	
Hedges'G (95% CI) in CFB		-0.10 (-0.45, 0.25)		-1.16 (-2.56, -0.15)	
p-value [3]		0.522		0.004	
					0.056

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-age-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	54	113	11	6	
Mean (StdDev)	2.7 (1.12)	2.7 (1.10)	2.1 (1.14)	2.8 (0.98)	
Median	3.0	3.0	2.0	2.5	
Min, Max	0, 4	0, 4	0, 4	2, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	54	113	11	6	
Mean (StdDev)	2.4 (1.16)	2.2 (1.22)	1.8 (0.87)	2.5 (0.55)	
Median	3.0	2.0	2.0	2.5	
Min, Max	0, 4	0, 4	0, 3	2, 3	
C2D1 CFB					
n	52	110	11	6	
LS Mean (StdErr) [2]	-0.30 (0.148)	-0.54 (0.109)	-0.66 (0.559)	-1.03 (0.815)	
95% CI [2]	-0.59, -0.01	-0.76, -0.32	-1.87, 0.54	-2.79, 0.73	
Difference (95% CI) in CFB [2]		-0.24 (-0.56, 0.07)		-0.36 (-1.73, 1.01)	
p-value [3]		0.132		0.576	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	53	104	10	6	
Mean (StdDev)	2.3 (1.17)	2.1 (1.18)	1.8 (1.14)	1.8 (0.41)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	1, 2	
C3D1 CFB					
n	51	103	10	6	
LS Mean (StdErr) [2]	-0.53 (0.159)	-0.62 (0.116)	-1.00 (0.438)	-2.00 (0.633)	
95% CI [2]	-0.84, -0.22	-0.85, -0.39	-1.95, -0.05	-3.38, -0.62	
Difference (95% CI) in CFB [2]		-0.09 (-0.43, 0.25)		-1.00 (-2.08, 0.08)	
p-value [3]		0.609		0.066	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	49	107	7	6	
Mean (StdDev)	2.4 (1.17)	2.1 (1.17)	2.3 (0.95)	1.7 (1.03)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 3	
C4D1 CFB					
n	47	105	7	6	
LS Mean (StdErr) [2]	-0.37 (0.179)	-0.67 (0.129)	-0.68 (0.682)	-2.58 (1.119)	
95% CI [2]	-0.72, -0.02	-0.92, -0.41	-2.22, 0.87	-5.11, -0.04	
Difference (95% CI) in CFB [2]		-0.29 (-0.67, 0.08)		-1.90 (-4.10, 0.30)	
p-value [3]		0.122		0.082	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	51	104	9	5	
Mean (StdDev)	2.2 (1.14)	2.1 (1.14)	2.4 (1.01)	1.4 (0.89)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 2	
C5D1 CFB					
n	50	100	9	5	
LS Mean (StdErr) [2]	-0.50 (0.185)	-0.70 (0.137)	-0.64 (0.502)	-2.66 (0.771)	
95% CI [2]	-0.86, -0.13	-0.97, -0.42	-1.76, 0.48	-4.38, -0.94	
Difference (95% CI) in CFB [2]		-0.20 (-0.59, 0.20)		-2.02 (-3.43, -0.61)	
p-value [3]		0.325		0.010	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	50	105	8	6	
Mean (StdDev)	2.3 (1.26)	1.8 (1.17)	2.4 (1.19)	1.7 (0.52)	
Median	2.0	2.0	2.5	2.0	
Min, Max	0, 4	0, 4	0, 4	1, 2	
C6D1 CFB					
n	49	101	8	6	
LS Mean (StdErr) [2]	-0.37 (0.188)	-0.85 (0.138)	-1.03 (0.512)	-2.63 (0.850)	
95% CI [2]	-0.74, 0.01	-1.13, -0.58	-2.17, 0.11	-4.53, -0.74	
Difference (95% CI) in CFB [2]		-0.49 (-0.89, -0.08)		-1.61 (-3.24, 0.03)	
p-value [3]		0.018		0.053	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	48	105	10	6	
Mean (StdDev)	2.3 (1.26)	1.9 (1.19)	2.0 (1.15)	1.7 (0.52)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	1, 2	
C7D1 CFB					
n	47	101	10	6	
LS Mean (StdErr) [2]	-0.29 (0.189)	-0.77 (0.135)	-0.36 (0.598)	-1.37 (0.865)	
95% CI [2]	-0.66, 0.08	-1.04, -0.51	-1.66, 0.95	-3.25, 0.52	
Difference (95% CI) in CFB [2]		-0.49 (-0.88, -0.09)		-1.01 (-2.48, 0.46)	
Hedges'G (95% CI) in CFB		-0.36 (-0.72, -0.02)		-0.48 (-1.69, 0.56)	
p-value [3]		0.017		0.159	
					0.351

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-age-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	54	113	11	6	
Mean (StdDev)	2.2 (1.37)	2.0 (1.34)	2.4 (1.29)	2.5 (0.55)	
Median	2.0	2.0	3.0	2.5	
Min, Max	0, 4	0, 4	0, 4	2, 3	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	54	113	11	6	
Mean (StdDev)	1.9 (1.33)	1.6 (1.30)	2.2 (1.08)	2.5 (1.52)	
Median	2.0	2.0	2.0	2.5	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	52	110	11	6	
LS Mean (StdErr) [2]	-0.22 (0.151)	-0.34 (0.112)	-0.46 (0.550)	-0.05 (0.802)	
95% CI [2]	-0.52, 0.08	-0.56, -0.12	-1.65, 0.73	-1.79, 1.68	
Difference (95% CI) in CFB [2]		-0.11 (-0.44, 0.21)		0.41 (-0.94, 1.76)	
p-value [3]		0.491		0.523	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	52	104	10	6	
Mean (StdDev)	1.7 (1.28)	1.5 (1.24)	2.1 (1.20)	1.7 (1.03)	
Median	2.0	1.5	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 3	
C3D1 CFB					
n	50	103	10	6	
LS Mean (StdErr) [2]	-0.46 (0.167)	-0.47 (0.122)	-1.03 (0.480)	-1.66 (0.695)	
95% CI [2]	-0.79, -0.13	-0.71, -0.23	-2.07, 0.02	-3.17, -0.15	
Difference (95% CI) in CFB [2]		-0.01 (-0.37, 0.35)		-0.63 (-1.82, 0.55)	
p-value [3]		0.957		0.265	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	49	107	7	6	
Mean (StdDev)	1.7 (1.38)	1.6 (1.32)	2.1 (1.21)	1.8 (1.33)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 3	
C4D1 CFB					
n	47	105	7	6	
LS Mean (StdErr) [2]	-0.49 (0.189)	-0.54 (0.137)	-0.97 (0.603)	-1.37 (0.989)	
95% CI [2]	-0.86, -0.11	-0.81, -0.27	-2.33, 0.40	-3.60, 0.87	
Difference (95% CI) in CFB [2]		-0.05 (-0.45, 0.34)		-0.40 (-2.34, 1.54)	
p-value [3]		0.792		0.653	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	51	104	9	5	
Mean (StdDev)	1.6 (1.35)	1.4 (1.27)	2.1 (1.27)	1.4 (1.14)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 3	
C5D1 CFB					
n	50	100	9	5	
LS Mean (StdErr) [2]	-0.53 (0.195)	-0.72 (0.145)	-0.97 (0.524)	-1.42 (0.805)	
95% CI [2]	-0.91, -0.14	-1.01, -0.44	-2.14, 0.20	-3.22, 0.37	
Difference (95% CI) in CFB [2]		-0.20 (-0.61, 0.22)		-0.46 (-1.93, 1.01)	
p-value [3]		0.357		0.505	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	50	105	8	6	
Mean (StdDev)	1.9 (1.43)	1.3 (1.22)	2.0 (1.31)	1.2 (0.98)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 3	
C6D1 CFB					
n	49	101	8	6	
LS Mean (StdErr) [2]	-0.25 (0.199)	-0.72 (0.146)	-0.90 (0.345)	-1.28 (0.572)	
95% CI [2]	-0.64, 0.15	-1.01, -0.44	-1.67, -0.13	-2.56, -0.01	
Difference (95% CI) in CFB [2]		-0.48 (-0.90, -0.05)		-0.38 (-1.48, 0.72)	
p-value [3]		0.028		0.459	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-age-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	48	105	10	6	
Mean (StdDev)	1.8 (1.37)	1.3 (1.32)	2.1 (1.37)	1.3 (1.03)	
Median	1.5	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 3	
C7D1 CFB					
n	47	101	10	6	
LS Mean (StdErr) [2]	-0.33 (0.187)	-0.65 (0.134)	-0.52 (0.480)	-1.20 (0.693)	
95% CI [2]	-0.70, 0.04	-0.91, -0.38	-1.57, 0.52	-2.71, 0.31	
Difference (95% CI) in CFB [2]		-0.31 (-0.71, 0.08)		-0.68 (-1.86, 0.50)	
Hedges'G (95% CI) in CFB		-0.23 (-0.59, 0.11)		-0.41 (-1.60, 0.64)	
p-value [3]		0.121		0.233	
					0.501

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-age-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	54	113	11	6	
Mean (StdDev)	2.4 (1.04)	2.5 (1.07)	2.5 (0.93)	2.8 (1.17)	
Median	2.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	1, 4	1, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	54	113	11	6	
Mean (StdDev)	1.9 (1.08)	1.8 (1.15)	2.0 (1.00)	2.0 (0.89)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	1, 3	
C2D1 CFB					
n	52	110	11	6	
LS Mean (StdErr) [2]	-0.44 (0.169)	-0.70 (0.125)	-0.72 (0.493)	-1.22 (0.719)	
95% CI [2]	-0.77, -0.10	-0.95, -0.45	-1.78, 0.35	-2.77, 0.33	
Difference (95% CI) in CFB [2]		-0.26 (-0.62, 0.10)		-0.50 (-1.71, 0.71)	
p-value [3]		0.161		0.388	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	53	103	10	6	
Mean (StdDev)	1.9 (1.08)	1.7 (1.07)	2.4 (1.26)	1.2 (0.98)	
Median	2.0	2.0	2.5	1.5	
Min, Max	0, 4	0, 4	0, 4	0, 2	
C3D1 CFB					
n	51	102	10	6	
LS Mean (StdErr) [2]	-0.60 (0.178)	-0.82 (0.130)	-0.33 (0.554)	-1.75 (0.801)	
95% CI [2]	-0.95, -0.25	-1.07, -0.56	-1.53, 0.88	-3.50, -0.01	
Difference (95% CI) in CFB [2]		-0.22 (-0.60, 0.16)		-1.42 (-2.79, -0.06)	
p-value [3]		0.262		0.042	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	49	107	7	6	
Mean (StdDev)	1.8 (1.09)	1.7 (1.14)	2.6 (1.13)	1.3 (1.21)	
Median	2.0	2.0	2.0	1.5	
Min, Max	0, 4	0, 4	1, 4	0, 3	
C4D1 CFB					
n	47	105	7	6	
LS Mean (StdErr) [2]	-0.71 (0.184)	-0.91 (0.133)	-0.33 (0.645)	-1.33 (1.058)	
95% CI [2]	-1.07, -0.35	-1.18, -0.65	-1.79, 1.13	-3.73, 1.06	
Difference (95% CI) in CFB [2]		-0.20 (-0.59, 0.18)		-1.00 (-3.08, 1.08)	
p-value [3]		0.298		0.305	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	51	104	9	5	
Mean (StdDev)	1.7 (1.16)	1.6 (1.15)	2.3 (1.12)	1.2 (1.10)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 3	0, 2	
C5D1 CFB					
n	50	100	9	5	
LS Mean (StdErr) [2]	-0.77 (0.193)	-1.08 (0.143)	-0.37 (0.693)	-1.20 (1.065)	
95% CI [2]	-1.15, -0.39	-1.36, -0.80	-1.91, 1.18	-3.57, 1.18	
Difference (95% CI) in CFB [2]		-0.31 (-0.73, 0.10)		-0.83 (-2.77, 1.12)	
p-value [3]		0.135		0.366	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	50	105	8	6	
Mean (StdDev)	1.9 (1.17)	1.5 (1.17)	2.3 (1.04)	1.2 (0.75)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	1, 4	0, 2	
C6D1 CFB					
n	49	101	8	6	
LS Mean (StdErr) [2]	-0.61 (0.188)	-1.11 (0.138)	-0.81 (0.577)	-1.47 (0.958)	
95% CI [2]	-0.98, -0.23	-1.39, -0.84	-2.09, 0.48	-3.61, 0.66	
Difference (95% CI) in CFB [2]		-0.51 (-0.91, -0.10)		-0.66 (-2.50, 1.18)	
p-value [3]		0.014		0.441	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	48	105	10	6	
Mean (StdDev)	1.8 (1.27)	1.5 (1.29)	2.3 (1.25)	1.2 (0.98)	
Median	2.0	2.0	2.0	1.5	
Min, Max	0, 4	0, 4	0, 4	0, 2	
C7D1 CFB					
n	47	101	10	6	
LS Mean (StdErr) [2]	-0.56 (0.221)	-0.99 (0.158)	-0.40 (0.663)	-1.77 (0.959)	
95% CI [2]	-0.99, -0.12	-1.30, -0.68	-1.85, 1.04	-3.86, 0.31	
Difference (95% CI) in CFB [2]		-0.43 (-0.90, 0.04)		-1.37 (-3.00, 0.26)	
Hedges'G (95% CI) in CFB		-0.27 (-0.63, 0.07)		-0.59 (-1.83, 0.44)	
p-value [3]		0.071		0.091	
					0.120

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	53	113	11	6	
Mean (StdDev)	2.1 (1.31)	2.2 (1.21)	2.0 (1.00)	2.2 (0.41)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 3	2, 3	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	54	113	11	6	
Mean (StdDev)	1.8 (1.27)	1.8 (1.19)	2.1 (1.04)	2.3 (0.82)	
Median	2.0	2.0	2.0	2.5	
Min, Max	0, 4	0, 4	1, 4	1, 3	
C2D1 CFB					
n	51	110	11	6	
LS Mean (StdErr) [2]	-0.17 (0.164)	-0.46 (0.121)	0.49 (0.438)	0.63 (0.639)	
95% CI [2]	-0.49, 0.16	-0.70, -0.23	-0.45, 1.44	-0.75, 2.01	
Difference (95% CI) in CFB [2]		-0.30 (-0.65, 0.06)		0.14 (-0.94, 1.21)	
p-value [3]		0.098		0.788	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	53	104	10	6	
Mean (StdDev)	1.7 (1.23)	1.6 (1.11)	2.3 (0.95)	1.3 (1.03)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 2	
C3D1 CFB					
n	50	103	10	6	
LS Mean (StdErr) [2]	-0.30 (0.158)	-0.60 (0.115)	1.20 (0.527)	0.41 (0.762)	
95% CI [2]	-0.62, 0.01	-0.83, -0.37	0.05, 2.35	-1.25, 2.07	
Difference (95% CI) in CFB [2]		-0.30 (-0.64, 0.04)		-0.79 (-2.09, 0.50)	
p-value [3]		0.085		0.208	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	49	107	7	6	
Mean (StdDev)	1.7 (1.26)	1.6 (1.25)	2.4 (0.98)	1.7 (1.37)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 3	
C4D1 CFB					
n	46	105	7	6	
LS Mean (StdErr) [2]	-0.36 (0.187)	-0.66 (0.134)	1.26 (0.649)	1.16 (1.065)	
95% CI [2]	-0.73, 0.01	-0.93, -0.40	-0.21, 2.73	-1.25, 3.57	
Difference (95% CI) in CFB [2]		-0.30 (-0.70, 0.09)		-0.10 (-2.19, 1.99)	
p-value [3]		0.125		0.916	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	51	104	9	5	
Mean (StdDev)	1.6 (1.11)	1.5 (1.16)	2.1 (1.05)	1.0 (1.00)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 3	0, 2	
C5D1 CFB					
n	49	100	9	5	
LS Mean (StdErr) [2]	-0.39 (0.185)	-0.72 (0.136)	1.12 (0.500)	0.45 (0.769)	
95% CI [2]	-0.76, -0.03	-0.99, -0.45	0.00, 2.23	-1.27, 2.16	
Difference (95% CI) in CFB [2]		-0.33 (-0.72, 0.07)		-0.67 (-2.08, 0.73)	
p-value [3]		0.103		0.310	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-age-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	50	105	8	6	
Mean (StdDev)	1.7 (1.22)	1.5 (1.25)	2.4 (1.06)	1.3 (0.52)	
Median	2.0	1.0	2.5	1.0	
Min, Max	0, 4	0, 4	1, 4	1, 2	
C6D1 CFB					
n	48	101	8	6	
LS Mean (StdErr) [2]	-0.35 (0.194)	-0.83 (0.142)	0.85 (0.312)	0.01 (0.519)	
95% CI [2]	-0.74, 0.03	-1.11, -0.55	0.15, 1.54	-1.14, 1.17	
Difference (95% CI) in CFB [2]		-0.48 (-0.90, -0.06)		-0.83 (-1.83, 0.17)	
p-value [3]		0.024		0.093	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-age-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	48	105	10	6	
Mean (StdDev)	1.7 (1.15)	1.6 (1.28)	2.0 (1.33)	1.2 (0.98)	
Median	2.0	2.0	2.0	1.5	
Min, Max	0, 4	0, 4	0, 4	0, 2	
C7D1 CFB					
n	46	101	10	6	
LS Mean (StdErr) [2]	-0.18 (0.203)	-0.57 (0.144)	1.04 (0.617)	0.45 (0.893)	
95% CI [2]	-0.58, 0.22	-0.86, -0.29	-0.30, 2.39	-1.50, 2.39	
Difference (95% CI) in CFB [2]		-0.40 (-0.83, 0.03)		-0.59 (-2.11, 0.92)	
Hedges'G (95% CI) in CFB		-0.28 (-0.63, 0.07)		-0.28 (-1.44, 0.79)	
p-value [3]		0.069		0.410	
					0.417

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-age-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	14	32	51	87	
Mean (StdDev)	3.2 (0.80)	2.1 (1.13)	2.6 (1.18)	2.4 (1.08)	
Median	3.0	2.0	3.0	2.0	
Min, Max	2, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	14	33	51	86	
Mean (StdDev)	2.6 (1.02)	1.8 (0.94)	2.2 (1.03)	1.6 (0.90)	
Median	2.5	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	13	31	50	85	
LS Mean (StdErr) [2]	-0.58 (0.297)	-0.35 (0.196)	-0.33 (0.175)	-0.67 (0.149)	
95% CI [2]	-1.18, 0.02	-0.75, 0.05	-0.68, 0.02	-0.96, -0.38	
Difference (95% CI) in CFB [2]		0.23 (-0.42, 0.89)		-0.34 (-0.72, 0.04)	
p-value [3]		0.472		0.081	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	28	48	82	
Mean (StdDev)	2.3 (1.23)	1.3 (0.86)	2.0 (1.09)	1.6 (0.96)	
Median	3.0	1.0	2.0	1.5	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C3D1 CFB					
n	14	28	47	81	
LS Mean (StdErr) [2]	-0.65 (0.373)	-0.70 (0.262)	-0.57 (0.186)	-0.74 (0.154)	
95% CI [2]	-1.41, 0.11	-1.23, -0.17	-0.94, -0.20	-1.05, -0.44	
Difference (95% CI) in CFB [2]		-0.05 (-0.87, 0.78)		-0.18 (-0.58, 0.23)	
p-value [3]		0.909		0.387	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	13	30	43	83	
Mean (StdDev)	2.5 (1.20)	1.4 (0.77)	2.2 (1.05)	1.4 (1.11)	
Median	3.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C4D1 CFB					
n	12	29	42	82	
LS Mean (StdErr) [2]	-0.60 (0.350)	-0.66 (0.242)	-0.41 (0.211)	-0.94 (0.169)	
95% CI [2]	-1.31, 0.11	-1.15, -0.18	-0.82, 0.01	-1.28, -0.61	
Difference (95% CI) in CFB [2]		-0.06 (-0.82, 0.70)		-0.53 (-0.98, -0.09)	
p-value [3]		0.871		0.020	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	31	45	77	
Mean (StdDev)	2.3 (1.11)	1.3 (0.86)	2.3 (1.23)	1.4 (1.02)	
Median	3.0	1.0	2.0	1.0	
Min, Max	1, 4	0, 3	0, 4	0, 4	
C5D1 CFB					
n	14	28	45	76	
LS Mean (StdErr) [2]	-0.69 (0.369)	-0.61 (0.261)	-0.26 (0.202)	-0.94 (0.169)	
95% CI [2]	-1.44, 0.05	-1.14, -0.08	-0.66, 0.14	-1.27, -0.60	
Difference (95% CI) in CFB [2]		0.08 (-0.73, 0.89)		-0.68 (-1.13, -0.24)	
p-value [3]		0.842		0.003	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	13	32	45	79	
Mean (StdDev)	2.5 (1.05)	1.4 (0.91)	2.1 (1.24)	1.5 (1.08)	
Median	3.0	1.0	2.0	1.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	12	29	45	78	
LS Mean (StdErr) [2]	-0.54 (0.396)	-0.52 (0.265)	-0.56 (0.197)	-0.96 (0.163)	
95% CI [2]	-1.34, 0.26	-1.06, 0.01	-0.95, -0.17	-1.28, -0.64	
Difference (95% CI) in CFB [2]		0.01 (-0.85, 0.88)		-0.40 (-0.84, 0.03)	
p-value [3]		0.973		0.068	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	14	34	44	77	
Mean (StdDev)	2.7 (1.07)	1.4 (0.88)	2.2 (1.15)	1.3 (0.99)	
Median	3.0	1.0	2.0	1.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	13	31	44	76	
LS Mean (StdErr) [2]	-0.31 (0.390)	-0.60 (0.255)	-0.38 (0.184)	-0.97 (0.152)	
95% CI [2]	-1.10, 0.47	-1.11, -0.08	-0.75, -0.02	-1.27, -0.67	
Difference (95% CI) in CFB [2]		-0.28 (-1.13, 0.57)		-0.59 (-0.99, -0.19)	
Hedges'G (95% CI) in CFB		-0.20 (-0.87, 0.46)		-0.45 (-0.84, -0.08)	
p-value [3]		0.507		0.004	
					0.434

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	14	32	51	87	
Mean (StdDev)	2.9 (0.83)	1.9 (1.24)	2.4 (1.22)	2.2 (1.09)	
Median	3.0	2.0	2.0	2.0	
Min, Max	2, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	14	33	51	86	
Mean (StdDev)	2.4 (1.22)	1.4 (1.00)	2.2 (1.10)	1.5 (0.99)	
Median	2.5	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	13	31	50	85	
LS Mean (StdErr) [2]	-0.37 (0.268)	-0.41 (0.177)	-0.13 (0.195)	-0.62 (0.166)	
95% CI [2]	-0.91, 0.17	-0.76, -0.05	-0.51, 0.26	-0.95, -0.29	
Difference (95% CI) in CFB [2]		-0.04 (-0.62, 0.55)		-0.49 (-0.92, -0.07)	
p-value [3]		0.901		0.023	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	28	48	82	
Mean (StdDev)	2.2 (1.37)	1.2 (1.09)	2.1 (1.20)	1.5 (0.96)	
Median	3.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	14	28	47	81	
LS Mean (StdErr) [2]	-0.72 (0.321)	-0.68 (0.225)	-0.18 (0.206)	-0.56 (0.170)	
95% CI [2]	-1.37, -0.07	-1.14, -0.22	-0.59, 0.23	-0.90, -0.22	
Difference (95% CI) in CFB [2]		0.04 (-0.67, 0.75)		-0.38 (-0.83, 0.07)	
p-value [3]		0.906		0.096	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	13	30	43	83	
Mean (StdDev)	2.5 (1.05)	1.3 (0.98)	2.1 (1.06)	1.3 (1.07)	
Median	3.0	1.0	2.0	1.0	
Min, Max	1, 4	0, 3	0, 4	0, 4	
C4D1 CFB					
n	12	29	42	82	
LS Mean (StdErr) [2]	-0.45 (0.380)	-0.65 (0.262)	-0.13 (0.202)	-0.73 (0.162)	
95% CI [2]	-1.22, 0.32	-1.18, -0.12	-0.53, 0.27	-1.05, -0.41	
Difference (95% CI) in CFB [2]		-0.20 (-1.02, 0.62)		-0.60 (-1.03, -0.17)	
p-value [3]		0.628		0.006	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	31	45	77	
Mean (StdDev)	2.2 (1.15)	1.2 (0.78)	2.1 (1.32)	1.4 (1.04)	
Median	2.0	1.0	2.0	1.0	
Min, Max	1, 4	0, 3	0, 4	0, 4	
C5D1 CFB					
n	14	28	45	76	
LS Mean (StdErr) [2]	-0.57 (0.319)	-0.52 (0.226)	-0.11 (0.208)	-0.63 (0.174)	
95% CI [2]	-1.21, 0.08	-0.97, -0.06	-0.52, 0.31	-0.97, -0.28	
Difference (95% CI) in CFB [2]		0.05 (-0.65, 0.75)		-0.52 (-0.98, -0.06)	
p-value [3]		0.888		0.026	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	13	32	45	79	
Mean (StdDev)	2.5 (0.97)	1.2 (0.93)	2.0 (1.22)	1.6 (1.13)	
Median	2.0	1.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	12	29	45	78	
LS Mean (StdErr) [2]	-0.36 (0.384)	-0.61 (0.257)	-0.11 (0.204)	-0.56 (0.169)	
95% CI [2]	-1.14, 0.42	-1.13, -0.09	-0.51, 0.30	-0.89, -0.22	
Difference (95% CI) in CFB [2]		-0.25 (-1.09, 0.58)		-0.45 (-0.90, 0.00)	
p-value [3]		0.544		0.051	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	14	34	44	77	
Mean (StdDev)	2.7 (0.83)	1.3 (1.05)	2.0 (1.24)	1.5 (1.11)	
Median	2.5	1.0	2.0	1.0	
Min, Max	2, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	13	31	44	76	
LS Mean (StdErr) [2]	0.02 (0.371)	-0.46 (0.243)	-0.15 (0.215)	-0.53 (0.177)	
95% CI [2]	-0.73, 0.77	-0.95, 0.03	-0.57, 0.28	-0.88, -0.18	
Difference (95% CI) in CFB [2]		-0.49 (-1.29, 0.32)		-0.38 (-0.85, 0.08)	
Hedges'G (95% CI) in CFB		-0.35 (-1.04, 0.30)		-0.25 (-0.64, 0.12)	
p-value [3]		0.232		0.102	
					0.821

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	14	32	51	87	
Mean (StdDev)	2.1 (1.03)	2.0 (1.12)	2.3 (1.17)	2.5 (1.04)	
Median	2.0	2.0	3.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	14	33	51	86	
Mean (StdDev)	1.9 (1.14)	1.7 (1.07)	2.1 (1.09)	1.9 (1.07)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	13	31	50	85	
LS Mean (StdErr) [2]	-0.05 (0.254)	-0.09 (0.168)	-0.20 (0.171)	-0.54 (0.145)	
95% CI [2]	-0.57, 0.46	-0.43, 0.25	-0.54, 0.13	-0.83, -0.26	
Difference (95% CI) in CFB [2]		-0.04 (-0.60, 0.52)		-0.34 (-0.71, 0.03)	
p-value [3]		0.886		0.072	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	28	48	82	
Mean (StdDev)	1.6 (0.91)	1.5 (1.17)	2.1 (1.05)	1.9 (1.07)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C3D1 CFB					
n	14	28	47	81	
LS Mean (StdErr) [2]	-0.51 (0.283)	-0.43 (0.198)	-0.03 (0.194)	-0.43 (0.160)	
95% CI [2]	-1.08, 0.06	-0.83, -0.03	-0.41, 0.35	-0.74, -0.11	
Difference (95% CI) in CFB [2]		0.08 (-0.55, 0.70)		-0.40 (-0.82, 0.02)	
p-value [3]		0.801		0.064	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	13	30	43	83	
Mean (StdDev)	1.9 (1.19)	1.3 (0.99)	2.2 (1.13)	1.9 (1.01)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C4D1 CFB					
n	12	29	42	82	
LS Mean (StdErr) [2]	-0.34 (0.316)	-0.71 (0.218)	-0.01 (0.206)	-0.42 (0.165)	
95% CI [2]	-0.99, 0.30	-1.15, -0.27	-0.42, 0.40	-0.74, -0.09	
Difference (95% CI) in CFB [2]		-0.36 (-1.05, 0.32)		-0.41 (-0.85, 0.03)	
p-value [3]		0.290		0.069	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	31	45	77	
Mean (StdDev)	1.7 (0.96)	1.4 (0.99)	2.1 (1.31)	1.9 (1.09)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	14	28	45	76	
LS Mean (StdErr) [2]	-0.33 (0.327)	-0.37 (0.231)	-0.11 (0.212)	-0.56 (0.177)	
95% CI [2]	-0.99, 0.33	-0.84, 0.09	-0.53, 0.31	-0.91, -0.21	
Difference (95% CI) in CFB [2]		-0.04 (-0.76, 0.67)		-0.45 (-0.92, 0.02)	
p-value [3]		0.903		0.059	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	13	32	45	79	
Mean (StdDev)	1.8 (0.83)	1.2 (1.01)	1.9 (1.29)	1.9 (1.14)	
Median	2.0	1.0	2.0	2.0	
Min, Max	1, 3	0, 3	0, 4	0, 4	
C6D1 CFB					
n	12	29	45	78	
LS Mean (StdErr) [2]	-0.42 (0.332)	-0.69 (0.222)	-0.15 (0.206)	-0.50 (0.171)	
95% CI [2]	-1.09, 0.25	-1.14, -0.24	-0.56, 0.26	-0.84, -0.16	
Difference (95% CI) in CFB [2]		-0.28 (-1.00, 0.45)		-0.35 (-0.81, 0.10)	
p-value [3]		0.446		0.130	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	14	34	44	77	
Mean (StdDev)	1.6 (0.85)	1.5 (1.05)	2.0 (1.19)	1.8 (1.13)	
Median	1.5	1.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C7D1 CFB					
n	13	31	44	76	
LS Mean (StdErr) [2]	-0.49 (0.388)	-0.36 (0.254)	-0.27 (0.212)	-0.73 (0.175)	
95% CI [2]	-1.28, 0.29	-0.87, 0.16	-0.69, 0.15	-1.08, -0.39	
Difference (95% CI) in CFB [2]		0.14 (-0.71, 0.98)		-0.46 (-0.92, -0.01)	
Hedges'G (95% CI) in CFB		0.10 (-0.57, 0.77)		-0.31 (-0.69, 0.06)	
p-value [3]		0.745		0.047	
					0.171

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	14	32	51	87	
Mean (StdDev)	2.3 (1.38)	2.4 (0.98)	2.1 (1.16)	2.0 (1.28)	
Median	2.0	3.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	14	33	51	85	
Mean (StdDev)	1.6 (1.34)	1.9 (1.01)	1.7 (1.13)	1.4 (1.14)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	13	31	50	84	
LS Mean (StdErr) [2]	-0.62 (0.321)	-0.34 (0.212)	-0.18 (0.192)	-0.56 (0.167)	
95% CI [2]	-1.27, 0.02	-0.77, 0.09	-0.56, 0.20	-0.89, -0.23	
Difference (95% CI) in CFB [2]		0.28 (-0.42, 0.99)		-0.38 (-0.80, 0.04)	
p-value [3]		0.418		0.077	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	28	48	82	
Mean (StdDev)	1.6 (1.35)	1.9 (1.23)	1.8 (1.28)	1.4 (1.10)	
Median	2.0	2.0	1.5	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	14	28	47	81	
LS Mean (StdErr) [2]	-0.32 (0.320)	-0.17 (0.225)	-0.15 (0.218)	-0.62 (0.179)	
95% CI [2]	-0.97, 0.32	-0.63, 0.28	-0.58, 0.28	-0.98, -0.27	
Difference (95% CI) in CFB [2]		0.15 (-0.56, 0.86)		-0.47 (-0.95, -0.00)	
p-value [3]		0.665		0.049	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	13	30	43	83	
Mean (StdDev)	1.8 (1.41)	1.9 (1.07)	1.8 (1.17)	1.4 (1.21)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	12	29	42	82	
LS Mean (StdErr) [2]	-0.36 (0.292)	-0.35 (0.201)	-0.29 (0.217)	-0.57 (0.174)	
95% CI [2]	-0.95, 0.23	-0.76, 0.06	-0.72, 0.14	-0.91, -0.23	
Difference (95% CI) in CFB [2]		0.01 (-0.62, 0.64)		-0.28 (-0.74, 0.18)	
p-value [3]		0.973		0.236	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	31	45	77	
Mean (StdDev)	1.9 (1.16)	1.5 (0.81)	1.8 (1.08)	1.4 (1.28)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C5D1 CFB					
n	14	28	45	76	
LS Mean (StdErr) [2]	-0.10 (0.286)	-0.82 (0.202)	-0.14 (0.223)	-0.57 (0.186)	
95% CI [2]	-0.68, 0.48	-1.23, -0.41	-0.58, 0.30	-0.94, -0.21	
Difference (95% CI) in CFB [2]		-0.72 (-1.35, -0.09)		-0.43 (-0.92, 0.06)	
p-value [3]		0.026		0.082	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	13	32	45	79	
Mean (StdDev)	1.9 (1.44)	1.6 (1.11)	1.7 (1.12)	1.3 (1.15)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	12	29	45	78	
LS Mean (StdErr) [2]	-0.00 (0.350)	-0.37 (0.234)	-0.21 (0.211)	-0.67 (0.174)	
95% CI [2]	-0.71, 0.71	-0.84, 0.10	-0.63, 0.21	-1.02, -0.33	
Difference (95% CI) in CFB [2]		-0.37 (-1.13, 0.39)		-0.46 (-0.93, 0.00)	
p-value [3]		0.333		0.050	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	14	34	44	77	
Mean (StdDev)	2.1 (1.21)	1.7 (1.17)	1.6 (1.04)	1.3 (1.26)	
Median	2.0	1.5	2.0	1.0	
Min, Max	0, 4	0, 4	0, 3	0, 4	
C7D1 CFB					
n	13	31	44	76	
LS Mean (StdErr) [2]	0.07 (0.335)	-0.41 (0.219)	-0.16 (0.222)	-0.51 (0.183)	
95% CI [2]	-0.61, 0.74	-0.85, 0.03	-0.60, 0.28	-0.87, -0.15	
Difference (95% CI) in CFB [2]		-0.48 (-1.21, 0.25)		-0.35 (-0.83, 0.13)	
Hedges'G (95% CI) in CFB		-0.39 (-1.08, 0.27)		-0.22 (-0.60, 0.15)	
p-value [3]		0.193		0.150	
					0.797

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	14	32	51	87	
Mean (StdDev)	3.0 (0.96)	3.0 (0.90)	3.2 (0.91)	3.4 (0.83)	
Median	3.0	3.0	3.0	4.0	
Min, Max	1, 4	1, 4	1, 4	1, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	14	33	51	86	
Mean (StdDev)	2.6 (1.01)	2.6 (0.97)	2.8 (0.95)	2.8 (1.12)	
Median	3.0	3.0	3.0	3.0	
Min, Max	1, 4	0, 4	1, 4	0, 4	
C2D1 CFB					
n	13	31	50	85	
LS Mean (StdErr) [2]	-0.40 (0.275)	-0.44 (0.182)	-0.35 (0.158)	-0.58 (0.135)	
95% CI [2]	-0.96, 0.16	-0.80, -0.07	-0.66, -0.03	-0.85, -0.31	
Difference (95% CI) in CFB [2]		-0.04 (-0.64, 0.57)		-0.23 (-0.58, 0.11)	
p-value [3]		0.904		0.182	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	28	48	82	
Mean (StdDev)	2.7 (1.16)	2.2 (0.99)	2.7 (1.10)	2.6 (1.11)	
Median	3.0	2.0	3.0	3.0	
Min, Max	0, 4	1, 4	0, 4	0, 4	
C3D1 CFB					
n	14	28	47	81	
LS Mean (StdErr) [2]	-0.31 (0.290)	-0.72 (0.203)	-0.44 (0.187)	-0.66 (0.154)	
95% CI [2]	-0.89, 0.28	-1.13, -0.31	-0.81, -0.07	-0.96, -0.35	
Difference (95% CI) in CFB [2]		-0.41 (-1.05, 0.23)		-0.22 (-0.63, 0.18)	
p-value [3]		0.203		0.281	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	13	30	43	83	
Mean (StdDev)	2.8 (1.30)	2.3 (0.96)	2.8 (1.09)	2.6 (1.16)	
Median	3.0	2.0	3.0	3.0	
Min, Max	1, 4	0, 4	1, 4	0, 4	
C4D1 CFB					
n	12	29	42	82	
LS Mean (StdErr) [2]	-0.33 (0.364)	-0.61 (0.251)	-0.44 (0.196)	-0.70 (0.157)	
95% CI [2]	-1.07, 0.41	-1.12, -0.10	-0.83, -0.05	-1.01, -0.39	
Difference (95% CI) in CFB [2]		-0.29 (-1.07, 0.50)		-0.26 (-0.68, 0.16)	
p-value [3]		0.468		0.224	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	31	45	77	
Mean (StdDev)	2.7 (1.29)	2.1 (1.01)	2.7 (1.19)	2.5 (1.19)	
Median	3.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	14	28	45	76	
LS Mean (StdErr) [2]	-0.21 (0.307)	-0.79 (0.217)	-0.46 (0.198)	-0.79 (0.166)	
95% CI [2]	-0.83, 0.41	-1.23, -0.35	-0.85, -0.07	-1.12, -0.47	
Difference (95% CI) in CFB [2]		-0.58 (-1.25, 0.09)		-0.33 (-0.77, 0.10)	
p-value [3]		0.089		0.133	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	13	32	45	79	
Mean (StdDev)	2.6 (1.04)	2.1 (0.95)	2.6 (1.13)	2.4 (1.26)	
Median	3.0	2.0	3.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	12	29	45	78	
LS Mean (StdErr) [2]	-0.60 (0.310)	-0.97 (0.207)	-0.51 (0.204)	-0.81 (0.169)	
95% CI [2]	-1.22, 0.03	-1.39, -0.55	-0.91, -0.11	-1.14, -0.47	
Difference (95% CI) in CFB [2]		-0.37 (-1.05, 0.30)		-0.30 (-0.75, 0.15)	
p-value [3]		0.271		0.191	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	14	34	44	77	
Mean (StdDev)	2.6 (1.15)	2.4 (0.92)	2.6 (1.08)	2.4 (1.20)	
Median	3.0	2.0	3.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	13	31	44	76	
LS Mean (StdErr) [2]	-0.35 (0.309)	-0.50 (0.202)	-0.55 (0.200)	-0.90 (0.165)	
95% CI [2]	-0.97, 0.27	-0.91, -0.09	-0.95, -0.16	-1.22, -0.57	
Difference (95% CI) in CFB [2]		-0.15 (-0.83, 0.52)		-0.35 (-0.78, 0.08)	
Hedges'G (95% CI) in CFB		-0.13 (-0.81, 0.53)		-0.25 (-0.63, 0.13)	
p-value [3]		0.650		0.114	
					0.613

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	14	32	51	87	
Mean (StdDev)	1.8 (1.05)	1.8 (0.97)	2.2 (1.14)	2.3 (1.04)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	14	33	51	86	
Mean (StdDev)	1.6 (1.22)	1.7 (0.92)	2.1 (1.05)	1.9 (1.01)	
Median	1.5	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	13	31	50	85	
LS Mean (StdErr) [2]	-0.16 (0.185)	-0.04 (0.123)	-0.16 (0.161)	-0.41 (0.138)	
95% CI [2]	-0.54, 0.21	-0.29, 0.20	-0.48, 0.16	-0.68, -0.14	
Difference (95% CI) in CFB [2]		0.12 (-0.29, 0.52)		-0.25 (-0.60, 0.10)	
p-value [3]		0.564		0.164	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	28	48	82	
Mean (StdDev)	1.5 (1.06)	1.5 (1.00)	2.0 (1.11)	1.7 (0.96)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	14	28	47	81	
LS Mean (StdErr) [2]	-0.43 (0.289)	-0.34 (0.203)	-0.21 (0.181)	-0.60 (0.149)	
95% CI [2]	-1.02, 0.15	-0.75, 0.07	-0.56, 0.15	-0.90, -0.31	
Difference (95% CI) in CFB [2]		0.10 (-0.54, 0.73)		-0.40 (-0.79, -0.00)	
p-value [3]		0.762		0.048	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	13	30	43	83	
Mean (StdDev)	1.7 (1.25)	1.5 (1.11)	2.0 (1.17)	1.9 (1.17)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	12	29	42	82	
LS Mean (StdErr) [2]	-0.09 (0.310)	-0.17 (0.214)	-0.19 (0.201)	-0.40 (0.161)	
95% CI [2]	-0.71, 0.54	-0.60, 0.27	-0.58, 0.21	-0.72, -0.08	
Difference (95% CI) in CFB [2]		-0.08 (-0.75, 0.59)		-0.21 (-0.64, 0.22)	
p-value [3]		0.805		0.330	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	31	45	77	
Mean (StdDev)	1.7 (1.29)	1.3 (0.90)	2.0 (1.22)	1.9 (1.15)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C5D1 CFB					
n	14	28	45	76	
LS Mean (StdErr) [2]	-0.07 (0.302)	-0.34 (0.214)	-0.26 (0.183)	-0.44 (0.153)	
95% CI [2]	-0.68, 0.54	-0.77, 0.09	-0.62, 0.10	-0.74, -0.14	
Difference (95% CI) in CFB [2]		-0.27 (-0.94, 0.39)		-0.18 (-0.58, 0.22)	
p-value [3]		0.409		0.378	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	13	32	45	79	
Mean (StdDev)	1.7 (1.18)	1.2 (0.87)	2.0 (1.07)	1.8 (1.21)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C6D1 CFB					
n	12	29	45	78	
LS Mean (StdErr) [2]	-0.20 (0.268)	-0.62 (0.179)	-0.23 (0.180)	-0.42 (0.149)	
95% CI [2]	-0.75, 0.34	-0.98, -0.25	-0.59, 0.13	-0.72, -0.13	
Difference (95% CI) in CFB [2]		-0.41 (-1.00, 0.17)		-0.19 (-0.59, 0.21)	
p-value [3]		0.160		0.346	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	14	34	44	77	
Mean (StdDev)	1.4 (1.09)	1.4 (1.02)	1.9 (1.08)	1.7 (1.13)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	13	31	44	76	
LS Mean (StdErr) [2]	-0.34 (0.268)	-0.33 (0.176)	-0.31 (0.182)	-0.56 (0.150)	
95% CI [2]	-0.89, 0.20	-0.68, 0.03	-0.67, 0.05	-0.86, -0.26	
Difference (95% CI) in CFB [2]		0.02 (-0.57, 0.60)		-0.25 (-0.64, 0.14)	
Hedges'G (95% CI) in CFB		0.02 (-0.65, 0.68)		-0.19 (-0.57, 0.18)	
p-value [3]		0.957		0.211	
					0.501

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	14	32	51	87	
Mean (StdDev)	2.1 (1.23)	2.6 (1.10)	2.9 (1.11)	2.9 (1.14)	
Median	2.0	3.0	3.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	14	33	51	85	
Mean (StdDev)	2.1 (1.17)	2.2 (1.04)	2.4 (1.08)	2.2 (1.13)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	13	31	50	84	
LS Mean (StdErr) [2]	0.02 (0.227)	-0.38 (0.150)	-0.38 (0.157)	-0.45 (0.136)	
95% CI [2]	-0.44, 0.48	-0.68, -0.07	-0.69, -0.07	-0.72, -0.18	
Difference (95% CI) in CFB [2]		-0.40 (-0.90, 0.10)		-0.07 (-0.41, 0.27)	
p-value [3]		0.113		0.692	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	28	48	82	
Mean (StdDev)	1.7 (1.11)	2.1 (1.08)	2.4 (1.11)	2.1 (1.27)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	14	28	47	81	
LS Mean (StdErr) [2]	-0.49 (0.278)	-0.44 (0.195)	-0.45 (0.193)	-0.61 (0.159)	
95% CI [2]	-1.05, 0.07	-0.84, -0.05	-0.83, -0.07	-0.93, -0.30	
Difference (95% CI) in CFB [2]		0.05 (-0.57, 0.66)		-0.16 (-0.58, 0.26)	
p-value [3]		0.876		0.454	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	13	30	43	83	
Mean (StdDev)	2.3 (1.03)	2.1 (1.04)	2.5 (1.20)	2.2 (1.29)	
Median	2.0	2.0	3.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	12	29	42	82	
LS Mean (StdErr) [2]	0.12 (0.325)	-0.56 (0.224)	-0.36 (0.219)	-0.52 (0.175)	
95% CI [2]	-0.54, 0.78	-1.01, -0.10	-0.79, 0.07	-0.86, -0.17	
Difference (95% CI) in CFB [2]		-0.68 (-1.38, 0.03)		-0.15 (-0.62, 0.31)	
p-value [3]		0.059		0.516	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	31	45	77	
Mean (StdDev)	2.0 (1.13)	2.0 (1.02)	2.6 (1.09)	2.4 (1.25)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	14	28	45	76	
LS Mean (StdErr) [2]	-0.11 (0.303)	-0.60 (0.214)	-0.27 (0.187)	-0.48 (0.157)	
95% CI [2]	-0.72, 0.51	-1.04, -0.17	-0.64, 0.10	-0.79, -0.17	
Difference (95% CI) in CFB [2]		-0.50 (-1.16, 0.17)		-0.21 (-0.62, 0.20)	
p-value [3]		0.140		0.318	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	13	32	45	79	
Mean (StdDev)	2.6 (1.12)	1.8 (1.08)	2.4 (1.25)	2.2 (1.24)	
Median	2.0	2.0	3.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	12	29	45	78	
LS Mean (StdErr) [2]	0.39 (0.314)	-0.82 (0.210)	-0.45 (0.198)	-0.58 (0.164)	
95% CI [2]	-0.24, 1.03	-1.24, -0.39	-0.84, -0.06	-0.91, -0.26	
Difference (95% CI) in CFB [2]		-1.21 (-1.90, -0.53)		-0.13 (-0.57, 0.30)	
p-value [3]		<0.001		0.543	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	14	34	44	77	
Mean (StdDev)	1.9 (1.03)	2.1 (0.92)	2.4 (1.22)	2.2 (1.27)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 3	1, 4	0, 4	0, 4	
C7D1 CFB					
n	13	31	44	76	
LS Mean (StdErr) [2]	-0.07 (0.256)	-0.36 (0.167)	-0.44 (0.203)	-0.55 (0.167)	
95% CI [2]	-0.59, 0.44	-0.69, -0.02	-0.85, -0.04	-0.88, -0.22	
Difference (95% CI) in CFB [2]		-0.28 (-0.84, 0.27)		-0.11 (-0.55, 0.33)	
Hedges'G (95% CI) in CFB		-0.30 (-0.99, 0.35)		-0.08 (-0.45, 0.30)	
p-value [3]		0.310		0.623	
					0.805

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	14	32	51	87	
Mean (StdDev)	2.1 (1.29)	2.6 (1.01)	2.3 (1.09)	2.7 (1.10)	
Median	2.0	3.0	2.0	3.0	
Min, Max	0, 4	1, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	14	33	50	86	
Mean (StdDev)	1.9 (1.27)	2.1 (0.86)	2.1 (1.20)	2.1 (1.25)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	1, 4	0, 4	0, 4	
C2D1 CFB					
n	13	31	49	85	
LS Mean (StdErr) [2]	-0.07 (0.241)	-0.45 (0.160)	-0.19 (0.156)	-0.61 (0.132)	
95% CI [2]	-0.56, 0.42	-0.77, -0.13	-0.50, 0.12	-0.88, -0.35	
Difference (95% CI) in CFB [2]		-0.38 (-0.91, 0.15)		-0.42 (-0.77, -0.08)	
p-value [3]		0.152		0.016	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	28	48	82	
Mean (StdDev)	1.9 (1.30)	1.9 (0.92)	2.2 (1.15)	1.9 (1.26)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	1, 4	0, 4	0, 4	
C3D1 CFB					
n	14	28	47	81	
LS Mean (StdErr) [2]	-0.21 (0.246)	-0.57 (0.173)	-0.12 (0.152)	-0.74 (0.125)	
95% CI [2]	-0.71, 0.29	-0.92, -0.22	-0.42, 0.18	-0.99, -0.49	
Difference (95% CI) in CFB [2]		-0.36 (-0.90, 0.18)		-0.62 (-0.95, -0.29)	
p-value [3]		0.188		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	13	30	43	83	
Mean (StdDev)	1.8 (1.21)	1.9 (0.99)	2.2 (1.15)	2.0 (1.24)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	12	29	42	82	
LS Mean (StdErr) [2]	-0.12 (0.246)	-0.46 (0.170)	-0.16 (0.185)	-0.61 (0.148)	
95% CI [2]	-0.62, 0.38	-0.81, -0.12	-0.52, 0.21	-0.90, -0.31	
Difference (95% CI) in CFB [2]		-0.34 (-0.88, 0.19)		-0.45 (-0.85, -0.06)	
p-value [3]		0.200		0.026	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	31	45	77	
Mean (StdDev)	1.9 (1.19)	1.7 (0.78)	2.2 (1.22)	2.0 (1.29)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C5D1 CFB					
n	14	28	45	76	
LS Mean (StdErr) [2]	-0.28 (0.292)	-0.77 (0.206)	-0.09 (0.179)	-0.62 (0.149)	
95% CI [2]	-0.87, 0.31	-1.19, -0.35	-0.45, 0.26	-0.92, -0.33	
Difference (95% CI) in CFB [2]		-0.49 (-1.13, 0.16)		-0.53 (-0.92, -0.13)	
p-value [3]		0.133		0.009	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	13	32	45	79	
Mean (StdDev)	1.8 (1.34)	1.8 (0.94)	2.1 (1.18)	1.9 (1.36)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	12	29	45	78	
LS Mean (StdErr) [2]	-0.15 (0.284)	-0.78 (0.190)	-0.28 (0.188)	-0.75 (0.156)	
95% CI [2]	-0.72, 0.43	-1.17, -0.40	-0.65, 0.10	-1.06, -0.44	
Difference (95% CI) in CFB [2]		-0.64 (-1.26, -0.02)		-0.48 (-0.89, -0.06)	
p-value [3]		0.044		0.025	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	14	34	44	77	
Mean (StdDev)	2.0 (1.24)	1.8 (0.97)	2.1 (1.18)	1.8 (1.37)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	13	31	44	76	
LS Mean (StdErr) [2]	0.05 (0.290)	-0.60 (0.190)	-0.21 (0.184)	-0.89 (0.152)	
95% CI [2]	-0.53, 0.64	-0.99, -0.22	-0.57, 0.16	-1.19, -0.59	
Difference (95% CI) in CFB [2]		-0.66 (-1.29, -0.03)		-0.68 (-1.07, -0.28)	
Hedges'G (95% CI) in CFB		-0.61 (-1.33, 0.03)		-0.52 (-0.91, -0.15)	
p-value [3]		0.042		<0.001	
					0.871

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	14	32	51	87	
Mean (StdDev)	1.9 (1.29)	1.9 (1.41)	2.2 (1.36)	2.2 (1.46)	
Median	2.0	2.0	2.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	14	33	51	86	
Mean (StdDev)	1.4 (1.22)	1.7 (1.26)	1.8 (1.44)	1.6 (1.46)	
Median	1.0	2.0	2.0	1.5	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	13	31	50	85	
LS Mean (StdErr) [2]	-0.54 (0.393)	-0.19 (0.260)	-0.39 (0.231)	-0.65 (0.197)	
95% CI [2]	-1.34, 0.25	-0.72, 0.33	-0.85, 0.06	-1.04, -0.26	
Difference (95% CI) in CFB [2]		0.35 (-0.51, 1.21)		-0.26 (-0.77, 0.25)	
p-value [3]		0.417		0.311	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	28	48	81	
Mean (StdDev)	1.6 (1.35)	1.8 (1.24)	1.8 (1.32)	1.5 (1.43)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	14	28	47	81	
LS Mean (StdErr) [2]	-0.45 (0.474)	-0.16 (0.333)	-0.30 (0.233)	-0.71 (0.192)	
95% CI [2]	-1.41, 0.51	-0.83, 0.52	-0.76, 0.16	-1.09, -0.33	
Difference (95% CI) in CFB [2]		0.29 (-0.76, 1.34)		-0.41 (-0.92, 0.09)	
p-value [3]		0.578		0.109	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	13	30	43	83	
Mean (StdDev)	2.3 (0.75)	1.7 (1.09)	1.8 (1.31)	1.5 (1.40)	
Median	2.0	2.0	2.0	1.0	
Min, Max	1, 3	0, 4	0, 4	0, 4	
C4D1 CFB					
n	12	29	42	82	
LS Mean (StdErr) [2]	0.02 (0.457)	-0.44 (0.316)	-0.31 (0.260)	-0.69 (0.208)	
95% CI [2]	-0.91, 0.94	-1.08, 0.20	-0.83, 0.20	-1.10, -0.28	
Difference (95% CI) in CFB [2]		-0.46 (-1.45, 0.53)		-0.38 (-0.93, 0.18)	
p-value [3]		0.357		0.180	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	31	44	78	
Mean (StdDev)	2.0 (1.20)	1.4 (1.23)	1.9 (1.23)	1.4 (1.34)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	14	28	44	77	
LS Mean (StdErr) [2]	-0.02 (0.452)	-0.71 (0.319)	-0.24 (0.243)	-0.81 (0.201)	
95% CI [2]	-0.94, 0.89	-1.35, -0.06	-0.72, 0.24	-1.21, -0.42	
Difference (95% CI) in CFB [2]		-0.68 (-1.68, 0.31)		-0.58 (-1.11, -0.04)	
p-value [3]		0.170		0.035	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	13	32	45	79	
Mean (StdDev)	2.1 (1.12)	1.4 (1.16)	1.9 (1.33)	1.5 (1.40)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	12	29	45	78	
LS Mean (StdErr) [2]	-0.20 (0.502)	-0.71 (0.336)	-0.16 (0.237)	-0.59 (0.196)	
95% CI [2]	-1.22, 0.82	-1.39, -0.03	-0.63, 0.31	-0.97, -0.20	
Difference (95% CI) in CFB [2]		-0.51 (-1.60, 0.59)		-0.43 (-0.95, 0.09)	
p-value [3]		0.354		0.107	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	14	34	44	77	
Mean (StdDev)	2.2 (1.12)	1.5 (1.19)	1.5 (1.32)	1.4 (1.38)	
Median	2.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	13	31	44	76	
LS Mean (StdErr) [2]	0.23 (0.453)	-0.39 (0.296)	-0.38 (0.238)	-0.73 (0.196)	
95% CI [2]	-0.69, 1.14	-0.99, 0.21	-0.85, 0.09	-1.12, -0.34	
Difference (95% CI) in CFB [2]		-0.62 (-1.60, 0.37)		-0.35 (-0.86, 0.17)	
Hedges'G (95% CI) in CFB		-0.37 (-1.06, 0.28)		-0.21 (-0.59, 0.17)	
p-value [3]		0.212		0.184	
					0.563

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	14	32	51	87	
Mean (StdDev)	2.6 (1.15)	2.3 (1.31)	2.5 (1.30)	2.8 (1.28)	
Median	3.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	14	33	51	86	
Mean (StdDev)	2.2 (1.12)	2.0 (1.13)	2.4 (1.28)	2.1 (1.37)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	13	31	50	85	
LS Mean (StdErr) [2]	-0.36 (0.379)	-0.27 (0.251)	-0.16 (0.181)	-0.64 (0.154)	
95% CI [2]	-1.12, 0.41	-0.78, 0.23	-0.52, 0.20	-0.95, -0.34	
Difference (95% CI) in CFB [2]		0.08 (-0.75, 0.91)		-0.48 (-0.88, -0.09)	
p-value [3]		0.842		0.017	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	28	48	81	
Mean (StdDev)	2.5 (1.19)	1.8 (1.22)	2.3 (1.22)	1.9 (1.32)	
Median	3.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	14	28	47	81	
LS Mean (StdErr) [2]	-0.08 (0.381)	-0.49 (0.268)	-0.25 (0.192)	-0.85 (0.158)	
95% CI [2]	-0.85, 0.70	-1.03, 0.05	-0.63, 0.13	-1.17, -0.54	
Difference (95% CI) in CFB [2]		-0.42 (-1.26, 0.43)		-0.61 (-1.03, -0.19)	
p-value [3]		0.324		0.005	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	13	30	43	83	
Mean (StdDev)	2.5 (1.13)	2.0 (1.08)	2.0 (1.36)	2.0 (1.43)	
Median	3.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	12	29	42	82	
LS Mean (StdErr) [2]	-0.05 (0.455)	-0.38 (0.314)	-0.35 (0.207)	-0.76 (0.166)	
95% CI [2]	-0.97, 0.87	-1.02, 0.26	-0.76, 0.06	-1.09, -0.43	
Difference (95% CI) in CFB [2]		-0.33 (-1.32, 0.66)		-0.41 (-0.86, 0.03)	
p-value [3]		0.502		0.066	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	31	44	78	
Mean (StdDev)	2.3 (1.23)	1.7 (0.98)	2.1 (1.23)	1.8 (1.35)	
Median	3.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	14	28	44	77	
LS Mean (StdErr) [2]	-0.06 (0.402)	-0.52 (0.284)	-0.29 (0.206)	-0.99 (0.170)	
95% CI [2]	-0.88, 0.75	-1.10, 0.06	-0.70, 0.12	-1.33, -0.65	
Difference (95% CI) in CFB [2]		-0.46 (-1.34, 0.43)		-0.70 (-1.15, -0.25)	
p-value [3]		0.301		0.003	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	13	32	45	79	
Mean (StdDev)	2.8 (0.90)	1.8 (1.14)	2.3 (1.32)	1.7 (1.39)	
Median	3.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	12	29	45	78	
LS Mean (StdErr) [2]	0.25 (0.467)	-0.46 (0.312)	-0.13 (0.197)	-0.92 (0.163)	
95% CI [2]	-0.70, 1.19	-1.09, 0.17	-0.52, 0.26	-1.24, -0.60	
Difference (95% CI) in CFB [2]		-0.71 (-1.73, 0.31)		-0.79 (-1.22, -0.35)	
p-value [3]		0.167		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	14	34	44	77	
Mean (StdDev)	2.8 (0.97)	1.8 (1.33)	2.0 (1.31)	1.8 (1.39)	
Median	3.0	2.0	2.0	1.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	13	31	44	76	
LS Mean (StdErr) [2]	0.21 (0.455)	-0.50 (0.298)	-0.42 (0.218)	-0.98 (0.180)	
95% CI [2]	-0.71, 1.13	-1.11, 0.10	-0.85, 0.01	-1.33, -0.62	
Difference (95% CI) in CFB [2]		-0.71 (-1.71, 0.28)		-0.56 (-1.03, -0.09)	
Hedges'G (95% CI) in CFB		-0.43 (-1.12, 0.23)		-0.36 (-0.75, 0.01)	
p-value [3]		0.152		0.020	
					0.766

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	14	32	51	87	
Mean (StdDev)	2.2 (1.25)	2.3 (1.15)	2.3 (1.41)	2.5 (1.08)	
Median	2.5	2.5	3.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	14	33	51	86	
Mean (StdDev)	2.1 (1.14)	1.9 (0.99)	2.1 (1.21)	1.8 (1.29)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	13	31	50	85	
LS Mean (StdErr) [2]	-0.21 (0.297)	-0.45 (0.197)	-0.11 (0.194)	-0.54 (0.165)	
95% CI [2]	-0.81, 0.39	-0.85, -0.06	-0.50, 0.27	-0.86, -0.21	
Difference (95% CI) in CFB [2]		-0.24 (-0.90, 0.41)		-0.43 (-0.85, -0.00)	
p-value [3]		0.453		0.050	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	28	48	81	
Mean (StdDev)	1.8 (1.37)	1.6 (1.03)	2.0 (1.41)	1.8 (1.15)	
Median	1.0	1.5	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	14	28	47	81	
LS Mean (StdErr) [2]	-0.18 (0.335)	-0.68 (0.235)	-0.24 (0.180)	-0.51 (0.149)	
95% CI [2]	-0.86, 0.50	-1.15, -0.20	-0.60, 0.11	-0.80, -0.21	
Difference (95% CI) in CFB [2]		-0.50 (-1.24, 0.24)		-0.26 (-0.66, 0.13)	
p-value [3]		0.183		0.184	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	13	30	43	83	
Mean (StdDev)	2.2 (1.21)	1.5 (0.97)	2.0 (1.39)	1.8 (1.29)	
Median	2.0	1.0	2.0	2.0	
Min, Max	1, 4	0, 3	0, 4	0, 4	
C4D1 CFB					
n	12	29	42	82	
LS Mean (StdErr) [2]	0.03 (0.391)	-0.79 (0.270)	-0.36 (0.222)	-0.63 (0.178)	
95% CI [2]	-0.76, 0.83	-1.34, -0.25	-0.80, 0.07	-0.99, -0.28	
Difference (95% CI) in CFB [2]		-0.83 (-1.68, 0.02)		-0.27 (-0.74, 0.20)	
p-value [3]		0.055		0.263	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	31	44	78	
Mean (StdDev)	1.9 (1.30)	1.4 (0.96)	2.1 (1.33)	1.7 (1.33)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C5D1 CFB					
n	14	28	44	77	
LS Mean (StdErr) [2]	-0.40 (0.356)	-0.92 (0.252)	-0.07 (0.221)	-0.75 (0.182)	
95% CI [2]	-1.12, 0.32	-1.43, -0.41	-0.51, 0.37	-1.11, -0.39	
Difference (95% CI) in CFB [2]		-0.52 (-1.30, 0.26)		-0.68 (-1.17, -0.20)	
p-value [3]		0.187		0.006	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	13	32	45	79	
Mean (StdDev)	2.4 (1.19)	1.3 (1.04)	2.2 (1.37)	1.7 (1.30)	
Median	3.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C6D1 CFB					
n	12	29	45	78	
LS Mean (StdErr) [2]	0.32 (0.400)	-0.89 (0.267)	0.06 (0.215)	-0.71 (0.178)	
95% CI [2]	-0.49, 1.13	-1.43, -0.35	-0.37, 0.48	-1.06, -0.36	
Difference (95% CI) in CFB [2]		-1.21 (-2.08, -0.34)		-0.77 (-1.24, -0.30)	
p-value [3]		0.008		0.002	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	14	34	44	77	
Mean (StdDev)	2.2 (1.19)	1.4 (1.05)	1.9 (1.37)	1.8 (1.37)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	13	31	44	76	
LS Mean (StdErr) [2]	0.21 (0.394)	-0.84 (0.258)	-0.15 (0.213)	-0.64 (0.176)	
95% CI [2]	-0.58, 1.01	-1.36, -0.31	-0.57, 0.27	-0.99, -0.29	
Difference (95% CI) in CFB [2]		-1.05 (-1.91, -0.19)		-0.49 (-0.95, -0.03)	
Hedges'G (95% CI) in CFB		-0.72 (-1.44, -0.07)		-0.33 (-0.71, 0.05)	
p-value [3]		0.018		0.037	
					0.255

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	14	32	51	87	
Mean (StdDev)	1.6 (1.22)	1.8 (1.37)	1.7 (1.61)	1.9 (1.55)	
Median	1.5	1.5	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	14	33	51	86	
Mean (StdDev)	1.5 (1.22)	1.7 (1.18)	1.8 (1.58)	1.5 (1.55)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	13	31	50	85	
LS Mean (StdErr) [2]	-0.07 (0.250)	-0.05 (0.165)	-0.06 (0.190)	-0.46 (0.161)	
95% CI [2]	-0.58, 0.43	-0.39, 0.28	-0.43, 0.32	-0.78, -0.14	
Difference (95% CI) in CFB [2]		0.02 (-0.53, 0.57)		-0.40 (-0.82, 0.01)	
p-value [3]		0.947		0.057	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	28	48	81	
Mean (StdDev)	1.4 (1.40)	1.4 (1.35)	1.6 (1.61)	1.4 (1.44)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	14	28	47	81	
LS Mean (StdErr) [2]	-0.04 (0.352)	-0.31 (0.247)	-0.29 (0.184)	-0.51 (0.152)	
95% CI [2]	-0.75, 0.68	-0.81, 0.20	-0.66, 0.07	-0.81, -0.21	
Difference (95% CI) in CFB [2]		-0.27 (-1.05, 0.51)		-0.22 (-0.62, 0.18)	
p-value [3]		0.491		0.280	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	13	30	43	83	
Mean (StdDev)	1.7 (1.03)	1.5 (1.31)	1.6 (1.43)	1.4 (1.44)	
Median	2.0	1.0	1.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C4D1 CFB					
n	12	29	42	82	
LS Mean (StdErr) [2]	0.29 (0.388)	-0.24 (0.268)	-0.36 (0.234)	-0.49 (0.188)	
95% CI [2]	-0.49, 1.08	-0.78, 0.31	-0.82, 0.11	-0.87, -0.12	
Difference (95% CI) in CFB [2]		-0.53 (-1.37, 0.31)		-0.14 (-0.64, 0.36)	
p-value [3]		0.210		0.584	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	31	44	77	
Mean (StdDev)	1.3 (1.22)	1.2 (1.28)	1.4 (1.48)	1.4 (1.41)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	14	28	44	76	
LS Mean (StdErr) [2]	-0.17 (0.404)	-0.58 (0.285)	-0.23 (0.231)	-0.46 (0.191)	
95% CI [2]	-0.99, 0.65	-1.16, -0.00	-0.69, 0.22	-0.84, -0.08	
Difference (95% CI) in CFB [2]		-0.41 (-1.30, 0.47)		-0.23 (-0.74, 0.28)	
p-value [3]		0.351		0.377	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	13	32	45	79	
Mean (StdDev)	1.5 (1.27)	1.0 (1.33)	1.4 (1.44)	1.5 (1.47)	
Median	2.0	0.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	12	29	45	78	
LS Mean (StdErr) [2]	0.05 (0.456)	-0.76 (0.305)	-0.39 (0.242)	-0.43 (0.200)	
95% CI [2]	-0.87, 0.97	-1.38, -0.14	-0.87, 0.09	-0.83, -0.03	
Difference (95% CI) in CFB [2]		-0.81 (-1.80, 0.19)		-0.04 (-0.58, 0.49)	
p-value [3]		0.108		0.876	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	14	34	44	77	
Mean (StdDev)	1.6 (1.34)	1.4 (1.40)	1.5 (1.45)	1.3 (1.46)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	13	31	44	76	
LS Mean (StdErr) [2]	0.17 (0.355)	-0.21 (0.232)	-0.15 (0.250)	-0.50 (0.206)	
95% CI [2]	-0.54, 0.89	-0.68, 0.26	-0.65, 0.34	-0.91, -0.09	
Difference (95% CI) in CFB [2]		-0.39 (-1.16, 0.39)		-0.35 (-0.89, 0.19)	
Hedges'G (95% CI) in CFB		-0.30 (-0.98, 0.36)		-0.20 (-0.58, 0.18)	
p-value [3]		0.317		0.206	
					0.996

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	14	32	51	87	
Mean (StdDev)	2.3 (1.38)	2.2 (1.08)	2.1 (1.31)	2.5 (1.21)	
Median	2.5	2.0	2.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	14	33	51	86	
Mean (StdDev)	1.8 (1.19)	1.9 (0.83)	1.8 (1.27)	1.8 (1.28)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 3	1, 4	0, 4	0, 4	
C2D1 CFB					
n	13	31	50	85	
LS Mean (StdErr) [2]	-0.51 (0.221)	-0.23 (0.146)	-0.28 (0.157)	-0.53 (0.134)	
95% CI [2]	-0.96, -0.07	-0.53, 0.06	-0.59, 0.03	-0.80, -0.27	
Difference (95% CI) in CFB [2]		0.28 (-0.21, 0.76)		-0.25 (-0.60, 0.09)	
p-value [3]		0.253		0.146	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	28	48	81	
Mean (StdDev)	2.1 (1.46)	1.7 (1.18)	1.8 (1.24)	1.6 (1.32)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	14	28	47	81	
LS Mean (StdErr) [2]	0.04 (0.313)	-0.48 (0.220)	-0.27 (0.170)	-0.77 (0.140)	
95% CI [2]	-0.59, 0.67	-0.93, -0.04	-0.60, 0.07	-1.04, -0.49	
Difference (95% CI) in CFB [2]		-0.52 (-1.22, 0.17)		-0.50 (-0.87, -0.13)	
p-value [3]		0.136		0.008	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	13	30	43	83	
Mean (StdDev)	2.1 (1.12)	1.5 (0.97)	1.8 (1.17)	1.7 (1.25)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C4D1 CFB					
n	12	29	42	82	
LS Mean (StdErr) [2]	-0.14 (0.311)	-0.67 (0.214)	-0.33 (0.176)	-0.77 (0.141)	
95% CI [2]	-0.77, 0.49	-1.10, -0.23	-0.67, 0.02	-1.05, -0.49	
Difference (95% CI) in CFB [2]		-0.53 (-1.20, 0.15)		-0.44 (-0.82, -0.07)	
p-value [3]		0.121		0.021	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	31	44	78	
Mean (StdDev)	2.0 (1.25)	1.3 (0.87)	1.7 (1.21)	1.6 (1.35)	
Median	2.0	1.0	1.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C5D1 CFB					
n	14	28	44	77	
LS Mean (StdErr) [2]	-0.22 (0.333)	-0.86 (0.235)	-0.43 (0.184)	-0.92 (0.152)	
95% CI [2]	-0.89, 0.46	-1.34, -0.38	-0.80, -0.07	-1.22, -0.62	
Difference (95% CI) in CFB [2]		-0.64 (-1.37, 0.09)		-0.49 (-0.90, -0.09)	
p-value [3]		0.084		0.017	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	13	32	45	79	
Mean (StdDev)	2.4 (1.26)	1.3 (1.11)	2.0 (1.20)	1.7 (1.42)	
Median	3.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	12	29	45	78	
LS Mean (StdErr) [2]	0.18 (0.354)	-0.82 (0.237)	-0.11 (0.191)	-0.79 (0.158)	
95% CI [2]	-0.53, 0.90	-1.30, -0.35	-0.49, 0.27	-1.11, -0.48	
Difference (95% CI) in CFB [2]		-1.01 (-1.78, -0.24)		-0.69 (-1.11, -0.26)	
p-value [3]		0.012		0.002	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	14	34	44	77	
Mean (StdDev)	2.3 (1.20)	1.5 (1.11)	1.8 (1.41)	1.5 (1.44)	
Median	3.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	13	31	44	76	
LS Mean (StdErr) [2]	0.19 (0.292)	-0.53 (0.191)	-0.27 (0.194)	-0.91 (0.160)	
95% CI [2]	-0.40, 0.78	-0.92, -0.14	-0.65, 0.11	-1.22, -0.59	
Difference (95% CI) in CFB [2]		-0.72 (-1.35, -0.08)		-0.64 (-1.05, -0.22)	
Hedges'G (95% CI) in CFB		-0.67 (-1.38, -0.02)		-0.47 (-0.85, -0.09)	
p-value [3]		0.028		0.003	
					0.934

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	14	32	51	87	
Mean (StdDev)	2.1 (1.29)	2.0 (1.03)	1.9 (1.43)	2.2 (1.39)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	14	33	51	86	
Mean (StdDev)	1.5 (1.09)	1.5 (1.06)	1.5 (1.25)	1.7 (1.35)	
Median	1.5	1.0	1.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C2D1 CFB					
n	13	31	50	85	
LS Mean (StdErr) [2]	-0.30 (0.267)	-0.33 (0.177)	-0.45 (0.174)	-0.55 (0.149)	
95% CI [2]	-0.84, 0.24	-0.69, 0.02	-0.79, -0.10	-0.84, -0.25	
Difference (95% CI) in CFB [2]		-0.04 (-0.62, 0.55)		-0.10 (-0.48, 0.28)	
p-value [3]		0.903		0.610	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	28	48	81	
Mean (StdDev)	1.8 (1.52)	1.4 (1.20)	1.6 (1.22)	1.5 (1.32)	
Median	2.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	14	28	47	81	
LS Mean (StdErr) [2]	-0.10 (0.307)	-0.55 (0.216)	-0.37 (0.179)	-0.67 (0.147)	
95% CI [2]	-0.72, 0.52	-0.99, -0.11	-0.72, -0.01	-0.96, -0.38	
Difference (95% CI) in CFB [2]		-0.45 (-1.13, 0.23)		-0.31 (-0.69, 0.08)	
p-value [3]		0.185		0.123	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	13	30	43	83	
Mean (StdDev)	1.6 (1.33)	1.2 (0.92)	1.6 (1.12)	1.5 (1.36)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C4D1 CFB					
n	12	29	42	82	
LS Mean (StdErr) [2]	-0.43 (0.328)	-0.84 (0.226)	-0.44 (0.185)	-0.72 (0.148)	
95% CI [2]	-1.09, 0.23	-1.30, -0.38	-0.80, -0.07	-1.02, -0.43	
Difference (95% CI) in CFB [2]		-0.41 (-1.12, 0.30)		-0.29 (-0.68, 0.11)	
p-value [3]		0.251		0.152	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	31	44	78	
Mean (StdDev)	1.6 (1.18)	1.1 (0.89)	1.5 (1.36)	1.6 (1.32)	
Median	2.0	1.0	1.0	1.5	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C5D1 CFB					
n	14	28	44	77	
LS Mean (StdErr) [2]	-0.32 (0.304)	-0.87 (0.215)	-0.31 (0.196)	-0.71 (0.162)	
95% CI [2]	-0.93, 0.30	-1.31, -0.44	-0.69, 0.08	-1.03, -0.39	
Difference (95% CI) in CFB [2]		-0.55 (-1.22, 0.11)		-0.40 (-0.83, 0.03)	
p-value [3]		0.101		0.067	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	13	32	45	79	
Mean (StdDev)	1.8 (1.41)	1.1 (1.06)	1.6 (1.23)	1.5 (1.44)	
Median	2.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C6D1 CFB					
n	12	29	45	78	
LS Mean (StdErr) [2]	-0.11 (0.342)	-0.83 (0.229)	-0.26 (0.196)	-0.77 (0.162)	
95% CI [2]	-0.80, 0.58	-1.29, -0.37	-0.65, 0.13	-1.10, -0.45	
Difference (95% CI) in CFB [2]		-0.72 (-1.46, 0.03)		-0.51 (-0.94, -0.08)	
p-value [3]		0.058		0.021	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	14	34	44	77	
Mean (StdDev)	1.7 (1.33)	1.3 (1.11)	1.5 (1.34)	1.3 (1.46)	
Median	2.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	13	31	44	76	
LS Mean (StdErr) [2]	-0.22 (0.337)	-0.61 (0.221)	-0.15 (0.201)	-0.73 (0.165)	
95% CI [2]	-0.90, 0.46	-1.06, -0.17	-0.55, 0.24	-1.06, -0.41	
Difference (95% CI) in CFB [2]		-0.39 (-1.13, 0.34)		-0.58 (-1.01, -0.15)	
Hedges'G (95% CI) in CFB		-0.31 (-1.00, 0.34)		-0.41 (-0.80, -0.04)	
p-value [3]		0.288		0.009	
					0.612

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	14	32	51	87	
Mean (StdDev)	3.1 (0.66)	2.8 (0.95)	3.0 (0.98)	2.9 (1.03)	
Median	3.0	3.0	3.0	3.0	
Min, Max	2, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	14	33	51	86	
Mean (StdDev)	2.6 (0.93)	2.7 (0.92)	2.5 (1.12)	2.4 (1.05)	
Median	2.5	3.0	3.0	2.0	
Min, Max	1, 4	1, 4	0, 4	0, 4	
C2D1 CFB					
n	13	31	50	85	
LS Mean (StdErr) [2]	-0.64 (0.243)	-0.26 (0.161)	-0.50 (0.154)	-0.56 (0.131)	
95% CI [2]	-1.13, -0.14	-0.58, 0.07	-0.80, -0.19	-0.82, -0.30	
Difference (95% CI) in CFB [2]		0.38 (-0.16, 0.91)		-0.06 (-0.40, 0.27)	
p-value [3]		0.161		0.713	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	28	48	81	
Mean (StdDev)	2.5 (0.92)	2.3 (0.85)	2.6 (1.10)	2.2 (1.22)	
Median	2.0	2.0	3.0	2.0	
Min, Max	1, 4	1, 4	0, 4	0, 4	
C3D1 CFB					
n	14	28	47	81	
LS Mean (StdErr) [2]	-0.51 (0.224)	-0.51 (0.158)	-0.31 (0.172)	-0.63 (0.142)	
95% CI [2]	-0.96, -0.05	-0.83, -0.19	-0.65, 0.03	-0.91, -0.35	
Difference (95% CI) in CFB [2]		-0.01 (-0.50, 0.49)		-0.33 (-0.70, 0.05)	
p-value [3]		0.981		0.086	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	13	30	43	83	
Mean (StdDev)	2.4 (1.04)	2.3 (1.09)	2.4 (1.28)	2.3 (1.25)	
Median	2.0	2.0	3.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	12	29	42	82	
LS Mean (StdErr) [2]	-0.66 (0.322)	-0.43 (0.222)	-0.56 (0.185)	-0.53 (0.148)	
95% CI [2]	-1.31, -0.00	-0.88, 0.02	-0.92, -0.19	-0.83, -0.24	
Difference (95% CI) in CFB [2]		0.22 (-0.47, 0.92)		0.02 (-0.37, 0.42)	
p-value [3]		0.520		0.910	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	31	45	78	
Mean (StdDev)	2.5 (1.13)	2.1 (1.03)	2.6 (1.01)	2.1 (1.37)	
Median	3.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C5D1 CFB					
n	14	28	45	77	
LS Mean (StdErr) [2]	-0.55 (0.337)	-0.76 (0.238)	-0.42 (0.193)	-0.98 (0.160)	
95% CI [2]	-1.23, 0.13	-1.24, -0.27	-0.80, -0.03	-1.30, -0.66	
Difference (95% CI) in CFB [2]		-0.21 (-0.95, 0.53)		-0.56 (-0.99, -0.14)	
p-value [3]		0.575		0.010	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	13	32	45	79	
Mean (StdDev)	2.6 (1.04)	2.0 (1.03)	2.6 (1.25)	2.2 (1.31)	
Median	3.0	2.0	3.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	12	29	45	78	
LS Mean (StdErr) [2]	-0.29 (0.313)	-0.73 (0.209)	-0.22 (0.207)	-0.57 (0.171)	
95% CI [2]	-0.92, 0.35	-1.16, -0.31	-0.63, 0.19	-0.91, -0.23	
Difference (95% CI) in CFB [2]		-0.45 (-1.13, 0.23)		-0.35 (-0.81, 0.10)	
p-value [3]		0.192		0.128	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	14	34	44	77	
Mean (StdDev)	2.5 (1.16)	2.0 (0.85)	2.5 (1.11)	2.2 (1.32)	
Median	2.5	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	13	31	44	76	
LS Mean (StdErr) [2]	-0.43 (0.292)	-0.75 (0.191)	-0.30 (0.193)	-0.64 (0.159)	
95% CI [2]	-1.02, 0.16	-1.14, -0.37	-0.68, 0.08	-0.95, -0.33	
Difference (95% CI) in CFB [2]		-0.32 (-0.96, 0.31)		-0.34 (-0.76, 0.07)	
Hedges'G (95% CI) in CFB		-0.30 (-0.98, 0.36)		-0.25 (-0.63, 0.12)	
p-value [3]		0.313		0.104	
					0.915

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	14	32	51	87	
Mean (StdDev)	2.4 (1.45)	2.3 (1.04)	2.5 (1.47)	2.5 (1.29)	
Median	2.5	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	14	33	51	86	
Mean (StdDev)	2.1 (1.35)	1.8 (1.28)	2.2 (1.20)	2.1 (1.39)	
Median	2.5	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	13	31	50	85	
LS Mean (StdErr) [2]	-0.07 (0.331)	-0.52 (0.219)	-0.33 (0.173)	-0.49 (0.147)	
95% CI [2]	-0.74, 0.60	-0.96, -0.08	-0.67, 0.01	-0.78, -0.20	
Difference (95% CI) in CFB [2]		-0.45 (-1.18, 0.27)		-0.16 (-0.54, 0.21)	
p-value [3]		0.214		0.394	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	28	48	81	
Mean (StdDev)	2.0 (1.41)	1.4 (1.10)	2.4 (1.14)	1.9 (1.33)	
Median	2.0	1.5	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	14	28	47	81	
LS Mean (StdErr) [2]	-0.52 (0.321)	-1.04 (0.225)	-0.09 (0.197)	-0.51 (0.162)	
95% CI [2]	-1.17, 0.13	-1.50, -0.59	-0.48, 0.30	-0.83, -0.19	
Difference (95% CI) in CFB [2]		-0.52 (-1.23, 0.19)		-0.42 (-0.85, 0.01)	
p-value [3]		0.147		0.056	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	13	30	43	83	
Mean (StdDev)	1.8 (1.52)	1.5 (1.22)	2.1 (1.24)	2.0 (1.46)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	12	29	42	82	
LS Mean (StdErr) [2]	-0.66 (0.337)	-0.86 (0.232)	-0.30 (0.191)	-0.53 (0.153)	
95% CI [2]	-1.34, 0.03	-1.33, -0.39	-0.68, 0.08	-0.83, -0.22	
Difference (95% CI) in CFB [2]		-0.21 (-0.94, 0.52)		-0.23 (-0.63, 0.18)	
p-value [3]		0.569		0.272	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	31	45	78	
Mean (StdDev)	1.7 (1.71)	1.5 (1.34)	2.1 (1.39)	1.9 (1.50)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	14	28	45	77	
LS Mean (StdErr) [2]	-0.73 (0.334)	-0.93 (0.236)	-0.25 (0.188)	-0.60 (0.156)	
95% CI [2]	-1.41, -0.06	-1.40, -0.45	-0.63, 0.12	-0.90, -0.29	
Difference (95% CI) in CFB [2]		-0.19 (-0.93, 0.54)		-0.34 (-0.75, 0.07)	
p-value [3]		0.596		0.103	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	13	32	45	79	
Mean (StdDev)	2.3 (1.55)	1.3 (1.19)	2.2 (1.24)	1.8 (1.44)	
Median	3.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	12	29	45	78	
LS Mean (StdErr) [2]	-0.05 (0.339)	-1.07 (0.227)	-0.12 (0.200)	-0.69 (0.166)	
95% CI [2]	-0.74, 0.64	-1.53, -0.61	-0.52, 0.27	-1.02, -0.36	
Difference (95% CI) in CFB [2]		-1.02 (-1.76, -0.28)		-0.57 (-1.01, -0.13)	
p-value [3]		0.008		0.012	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	14	34	44	77	
Mean (StdDev)	1.9 (1.56)	1.3 (1.31)	2.1 (1.40)	1.6 (1.45)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	13	31	44	76	
LS Mean (StdErr) [2]	-0.58 (0.349)	-1.06 (0.229)	-0.21 (0.210)	-0.65 (0.173)	
95% CI [2]	-1.29, 0.12	-1.52, -0.60	-0.62, 0.21	-0.99, -0.31	
Difference (95% CI) in CFB [2]		-0.47 (-1.23, 0.29)		-0.44 (-0.90, 0.01)	
Hedges'G (95% CI) in CFB		-0.37 (-1.06, 0.29)		-0.30 (-0.68, 0.07)	
p-value [3]		0.217		0.054	
					0.863

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	14	32	51	87	
Mean (StdDev)	2.6 (0.93)	2.9 (0.88)	2.8 (1.20)	3.0 (1.00)	
Median	2.5	3.0	3.0	3.0	
Min, Max	1, 4	1, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	14	33	51	86	
Mean (StdDev)	2.1 (1.17)	2.2 (1.21)	2.3 (1.13)	2.3 (1.25)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	13	31	50	85	
LS Mean (StdErr) [2]	-0.51 (0.296)	-0.69 (0.196)	-0.61 (0.164)	-0.75 (0.140)	
95% CI [2]	-1.11, 0.09	-1.09, -0.30	-0.93, -0.29	-1.03, -0.47	
Difference (95% CI) in CFB [2]		-0.18 (-0.83, 0.47)		-0.14 (-0.50, 0.22)	
p-value [3]		0.576		0.443	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	28	48	81	
Mean (StdDev)	2.5 (1.41)	2.1 (1.03)	2.4 (1.16)	2.0 (1.28)	
Median	3.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	14	28	47	81	
LS Mean (StdErr) [2]	-0.25 (0.365)	-0.95 (0.256)	-0.42 (0.175)	-0.89 (0.144)	
95% CI [2]	-0.99, 0.49	-1.47, -0.43	-0.77, -0.08	-1.17, -0.60	
Difference (95% CI) in CFB [2]		-0.69 (-1.50, 0.11)		-0.47 (-0.85, -0.09)	
p-value [3]		0.090		0.016	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	13	30	43	83	
Mean (StdDev)	2.5 (0.97)	2.0 (0.98)	2.4 (1.24)	2.1 (1.32)	
Median	3.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	12	29	42	82	
LS Mean (StdErr) [2]	-0.31 (0.332)	-1.01 (0.229)	-0.37 (0.189)	-0.91 (0.151)	
95% CI [2]	-0.98, 0.36	-1.47, -0.55	-0.74, 0.01	-1.21, -0.61	
Difference (95% CI) in CFB [2]		-0.70 (-1.42, 0.02)		-0.54 (-0.95, -0.14)	
p-value [3]		0.056		0.008	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	31	45	77	
Mean (StdDev)	2.2 (1.32)	1.8 (1.01)	2.3 (1.15)	2.1 (1.27)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	14	28	45	76	
LS Mean (StdErr) [2]	-0.39 (0.322)	-1.05 (0.228)	-0.46 (0.183)	-0.97 (0.152)	
95% CI [2]	-1.04, 0.26	-1.51, -0.59	-0.82, -0.10	-1.27, -0.67	
Difference (95% CI) in CFB [2]		-0.66 (-1.36, 0.05)		-0.51 (-0.91, -0.11)	
p-value [3]		0.069		0.013	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	13	32	45	79	
Mean (StdDev)	2.7 (0.95)	1.8 (1.02)	2.4 (1.21)	2.0 (1.41)	
Median	3.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	12	29	45	78	
LS Mean (StdErr) [2]	-0.08 (0.323)	-1.23 (0.216)	-0.40 (0.194)	-1.06 (0.161)	
95% CI [2]	-0.73, 0.58	-1.67, -0.79	-0.78, -0.01	-1.37, -0.74	
Difference (95% CI) in CFB [2]		-1.15 (-1.86, -0.45)		-0.66 (-1.09, -0.23)	
p-value [3]		0.002		0.003	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	14	34	44	77	
Mean (StdDev)	2.4 (1.22)	1.9 (1.07)	2.2 (1.37)	1.9 (1.44)	
Median	2.5	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	13	31	44	76	
LS Mean (StdErr) [2]	-0.25 (0.334)	-0.90 (0.218)	-0.41 (0.196)	-0.97 (0.162)	
95% CI [2]	-0.92, 0.42	-1.34, -0.46	-0.80, -0.02	-1.29, -0.65	
Difference (95% CI) in CFB [2]		-0.65 (-1.37, 0.08)		-0.56 (-0.98, -0.14)	
Hedges'G (95% CI) in CFB		-0.52 (-1.23, 0.13)		-0.41 (-0.79, -0.03)	
p-value [3]		0.080		0.010	
					0.802

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	14	32	51	87	
Mean (StdDev)	2.8 (0.97)	3.1 (0.80)	3.2 (0.90)	3.2 (0.99)	
Median	3.0	3.0	3.0	3.0	
Min, Max	1, 4	2, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	14	33	51	86	
Mean (StdDev)	2.3 (1.14)	2.3 (0.76)	2.7 (0.94)	2.4 (1.18)	
Median	2.0	2.0	3.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	13	31	50	85	
LS Mean (StdErr) [2]	-0.60 (0.233)	-0.88 (0.154)	-0.38 (0.153)	-0.72 (0.131)	
95% CI [2]	-1.07, -0.12	-1.19, -0.57	-0.68, -0.07	-0.98, -0.46	
Difference (95% CI) in CFB [2]		-0.28 (-0.80, 0.23)		-0.34 (-0.68, -0.01)	
p-value [3]		0.270		0.045	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	28	48	81	
Mean (StdDev)	2.3 (1.23)	2.1 (0.90)	2.5 (1.05)	2.1 (1.26)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	14	28	47	81	
LS Mean (StdErr) [2]	-0.58 (0.299)	-1.14 (0.210)	-0.53 (0.173)	-0.92 (0.143)	
95% CI [2]	-1.19, 0.02	-1.57, -0.72	-0.88, -0.19	-1.20, -0.63	
Difference (95% CI) in CFB [2]		-0.56 (-1.22, 0.10)		-0.38 (-0.76, -0.00)	
p-value [3]		0.095		0.048	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	13	30	43	83	
Mean (StdDev)	2.3 (1.25)	1.8 (0.81)	2.5 (1.12)	2.2 (1.22)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C4D1 CFB					
n	12	29	42	82	
LS Mean (StdErr) [2]	-0.95 (0.274)	-1.52 (0.189)	-0.54 (0.178)	-0.93 (0.143)	
95% CI [2]	-1.50, -0.39	-1.90, -1.13	-0.90, -0.19	-1.21, -0.65	
Difference (95% CI) in CFB [2]		-0.57 (-1.16, 0.03)		-0.39 (-0.77, -0.01)	
p-value [3]		0.060		0.046	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	31	45	78	
Mean (StdDev)	2.1 (1.36)	1.8 (0.82)	2.5 (1.25)	2.3 (1.29)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C5D1 CFB					
n	14	28	45	77	
LS Mean (StdErr) [2]	-0.78 (0.284)	-1.35 (0.201)	-0.44 (0.198)	-0.82 (0.164)	
95% CI [2]	-1.36, -0.21	-1.75, -0.94	-0.83, -0.05	-1.14, -0.49	
Difference (95% CI) in CFB [2]		-0.56 (-1.19, 0.06)		-0.38 (-0.81, 0.06)	
p-value [3]		0.075		0.089	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	13	32	45	79	
Mean (StdDev)	2.5 (1.20)	1.7 (1.00)	2.6 (1.15)	2.2 (1.35)	
Median	3.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	12	29	45	78	
LS Mean (StdErr) [2]	-0.52 (0.347)	-1.63 (0.232)	-0.38 (0.195)	-0.88 (0.162)	
95% CI [2]	-1.23, 0.18	-2.10, -1.16	-0.77, 0.01	-1.20, -0.56	
Difference (95% CI) in CFB [2]		-1.11 (-1.86, -0.35)		-0.50 (-0.93, -0.07)	
p-value [3]		0.005		0.022	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	14	34	44	77	
Mean (StdDev)	2.6 (1.45)	1.9 (1.01)	2.3 (1.29)	2.0 (1.38)	
Median	3.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	13	31	44	76	
LS Mean (StdErr) [2]	-0.32 (0.357)	-1.20 (0.234)	-0.54 (0.201)	-0.98 (0.166)	
95% CI [2]	-1.04, 0.40	-1.68, -0.73	-0.94, -0.14	-1.31, -0.65	
Difference (95% CI) in CFB [2]		-0.89 (-1.66, -0.11)		-0.45 (-0.88, -0.01)	
Hedges'G (95% CI) in CFB		-0.67 (-1.39, -0.02)		-0.31 (-0.70, 0.06)	
p-value [3]		0.027		0.044	
					0.269

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	14	32	51	87	
Mean (StdDev)	1.6 (1.45)	1.1 (1.24)	2.5 (1.41)	2.2 (1.48)	
Median	1.5	1.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	14	33	51	86	
Mean (StdDev)	1.4 (1.40)	1.0 (1.13)	2.1 (1.41)	1.7 (1.47)	
Median	1.0	1.0	2.0	1.5	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	13	31	50	85	
LS Mean (StdErr) [2]	-0.11 (0.353)	-0.19 (0.233)	-0.00 (0.185)	-0.11 (0.157)	
95% CI [2]	-0.82, 0.60	-0.66, 0.29	-0.37, 0.36	-0.42, 0.20	
Difference (95% CI) in CFB [2]		-0.08 (-0.85, 0.70)		-0.11 (-0.51, 0.30)	
p-value [3]		0.842		0.604	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	28	48	81	
Mean (StdDev)	1.5 (1.36)	0.9 (1.15)	2.2 (1.36)	1.6 (1.47)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	14	28	47	81	
LS Mean (StdErr) [2]	-0.37 (0.413)	-0.42 (0.290)	0.00 (0.202)	-0.29 (0.167)	
95% CI [2]	-1.21, 0.46	-1.00, 0.17	-0.40, 0.40	-0.62, 0.04	
Difference (95% CI) in CFB [2]		-0.04 (-0.96, 0.87)		-0.29 (-0.73, 0.14)	
p-value [3]		0.924		0.187	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	13	30	43	83	
Mean (StdDev)	1.7 (1.38)	0.8 (1.03)	1.9 (1.26)	1.8 (1.47)	
Median	1.0	0.5	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	12	29	42	82	
LS Mean (StdErr) [2]	0.03 (0.369)	-0.36 (0.255)	-0.30 (0.204)	-0.18 (0.163)	
95% CI [2]	-0.71, 0.78	-0.87, 0.16	-0.70, 0.11	-0.50, 0.14	
Difference (95% CI) in CFB [2]		-0.39 (-1.19, 0.41)		0.12 (-0.32, 0.55)	
p-value [3]		0.329		0.600	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	31	45	78	
Mean (StdDev)	1.7 (1.29)	0.7 (1.03)	1.9 (1.39)	1.7 (1.44)	
Median	2.0	0.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	14	28	45	77	
LS Mean (StdErr) [2]	-0.07 (0.441)	-0.28 (0.312)	-0.28 (0.208)	-0.32 (0.173)	
95% CI [2]	-0.96, 0.82	-0.91, 0.35	-0.69, 0.13	-0.67, 0.02	
Difference (95% CI) in CFB [2]		-0.21 (-1.18, 0.76)		-0.04 (-0.50, 0.41)	
p-value [3]		0.663		0.850	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	13	32	45	79	
Mean (StdDev)	1.7 (1.65)	0.7 (1.00)	2.0 (1.41)	1.7 (1.39)	
Median	1.0	0.0	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C6D1 CFB					
n	12	29	45	78	
LS Mean (StdErr) [2]	0.01 (0.458)	-0.44 (0.306)	-0.32 (0.220)	-0.38 (0.182)	
95% CI [2]	-0.92, 0.93	-1.06, 0.18	-0.76, 0.11	-0.74, -0.02	
Difference (95% CI) in CFB [2]		-0.45 (-1.44, 0.55)		-0.06 (-0.54, 0.43)	
p-value [3]		0.372		0.818	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	14	34	44	77	
Mean (StdDev)	1.6 (1.45)	0.8 (0.91)	2.1 (1.51)	1.5 (1.47)	
Median	1.5	1.0	2.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C7D1 CFB					
n	13	31	44	76	
LS Mean (StdErr) [2]	-0.03 (0.417)	-0.38 (0.273)	0.06 (0.226)	-0.26 (0.186)	
95% CI [2]	-0.87, 0.81	-0.93, 0.17	-0.39, 0.51	-0.63, 0.11	
Difference (95% CI) in CFB [2]		-0.35 (-1.26, 0.56)		-0.32 (-0.81, 0.16)	
Hedges'G (95% CI) in CFB		-0.23 (-0.91, 0.43)		-0.20 (-0.58, 0.17)	
p-value [3]		0.443		0.191	
					0.792

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	14	32	51	87	
Mean (StdDev)	1.3 (0.91)	1.3 (1.05)	1.9 (1.30)	2.0 (1.36)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	14	33	51	86	
Mean (StdDev)	1.6 (1.01)	1.1 (0.98)	1.5 (1.12)	1.5 (1.34)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C2D1 CFB					
n	13	31	50	85	
LS Mean (StdErr) [2]	0.16 (0.270)	-0.20 (0.179)	-0.45 (0.134)	-0.55 (0.114)	
95% CI [2]	-0.38, 0.71	-0.56, 0.16	-0.71, -0.18	-0.78, -0.33	
Difference (95% CI) in CFB [2]		-0.36 (-0.96, 0.23)		-0.10 (-0.40, 0.19)	
p-value [3]		0.224		0.482	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	28	48	81	
Mean (StdDev)	1.3 (1.03)	0.9 (0.96)	1.6 (1.19)	1.2 (1.28)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C3D1 CFB					
n	14	28	47	81	
LS Mean (StdErr) [2]	-0.17 (0.289)	-0.33 (0.203)	-0.34 (0.191)	-0.83 (0.157)	
95% CI [2]	-0.76, 0.41	-0.75, 0.08	-0.71, 0.04	-1.15, -0.52	
Difference (95% CI) in CFB [2]		-0.16 (-0.80, 0.48)		-0.50 (-0.91, -0.08)	
p-value [3]		0.614		0.019	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	13	30	43	83	
Mean (StdDev)	1.3 (1.03)	0.7 (0.80)	1.7 (1.19)	1.3 (1.28)	
Median	2.0	0.5	1.0	1.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C4D1 CFB					
n	12	29	42	82	
LS Mean (StdErr) [2]	-0.24 (0.282)	-0.58 (0.195)	-0.25 (0.210)	-0.78 (0.168)	
95% CI [2]	-0.81, 0.33	-0.98, -0.19	-0.67, 0.16	-1.11, -0.44	
Difference (95% CI) in CFB [2]		-0.34 (-0.95, 0.27)		-0.52 (-0.97, -0.07)	
p-value [3]		0.264		0.023	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	31	45	78	
Mean (StdDev)	1.5 (1.19)	0.6 (0.91)	1.5 (1.14)	1.2 (1.29)	
Median	2.0	0.0	1.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C5D1 CFB					
n	14	28	45	77	
LS Mean (StdErr) [2]	-0.02 (0.277)	-0.62 (0.195)	-0.47 (0.186)	-0.87 (0.155)	
95% CI [2]	-0.58, 0.54	-1.01, -0.22	-0.84, -0.10	-1.18, -0.56	
Difference (95% CI) in CFB [2]		-0.59 (-1.20, 0.01)		-0.40 (-0.81, 0.01)	
p-value [3]		0.055		0.054	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	13	32	45	79	
Mean (StdDev)	1.5 (1.27)	0.7 (0.93)	1.6 (1.16)	1.3 (1.25)	
Median	2.0	0.0	1.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C6D1 CFB					
n	12	29	45	78	
LS Mean (StdErr) [2]	-0.03 (0.320)	-0.58 (0.214)	-0.37 (0.183)	-0.79 (0.151)	
95% CI [2]	-0.67, 0.62	-1.01, -0.14	-0.73, -0.01	-1.08, -0.49	
Difference (95% CI) in CFB [2]		-0.55 (-1.25, 0.15)		-0.42 (-0.82, -0.01)	
p-value [3]		0.119		0.043	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	14	34	44	77	
Mean (StdDev)	1.1 (1.10)	0.8 (0.98)	1.4 (1.13)	1.1 (1.24)	
Median	1.0	0.0	1.0	1.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C7D1 CFB					
n	13	31	44	76	
LS Mean (StdErr) [2]	-0.30 (0.272)	-0.48 (0.178)	-0.41 (0.187)	-0.75 (0.154)	
95% CI [2]	-0.85, 0.25	-0.84, -0.12	-0.79, -0.04	-1.06, -0.45	
Difference (95% CI) in CFB [2]		-0.18 (-0.77, 0.42)		-0.34 (-0.74, 0.07)	
Hedges'G (95% CI) in CFB		-0.17 (-0.85, 0.48)		-0.26 (-0.64, 0.12)	
p-value [3]		0.553		0.102	
					0.705

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	14	32	51	87	
Mean (StdDev)	0.9 (0.92)	1.1 (1.16)	1.4 (1.35)	1.6 (1.55)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	14	33	51	86	
Mean (StdDev)	1.4 (1.34)	0.9 (1.09)	1.2 (1.35)	1.3 (1.45)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	13	31	50	85	
LS Mean (StdErr) [2]	0.34 (0.295)	0.03 (0.195)	-0.05 (0.164)	-0.17 (0.140)	
95% CI [2]	-0.26, 0.93	-0.37, 0.42	-0.37, 0.27	-0.45, 0.11	
Difference (95% CI) in CFB [2]		-0.31 (-0.96, 0.34)		-0.12 (-0.48, 0.24)	
p-value [3]		0.338		0.511	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	28	48	81	
Mean (StdDev)	0.8 (1.01)	0.8 (0.93)	1.1 (1.25)	1.1 (1.33)	
Median	0.0	0.5	1.0	0.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C3D1 CFB					
n	14	28	47	81	
LS Mean (StdErr) [2]	-0.03 (0.330)	-0.14 (0.232)	-0.12 (0.189)	-0.41 (0.156)	
95% CI [2]	-0.69, 0.64	-0.60, 0.33	-0.49, 0.26	-0.72, -0.11	
Difference (95% CI) in CFB [2]		-0.11 (-0.84, 0.62)		-0.30 (-0.71, 0.11)	
p-value [3]		0.764		0.155	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	13	30	43	83	
Mean (StdDev)	0.9 (0.86)	0.7 (1.06)	1.5 (1.35)	1.2 (1.28)	
Median	1.0	0.0	1.0	1.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	
C4D1 CFB					
n	12	29	42	82	
LS Mean (StdErr) [2]	-0.24 (0.352)	-0.30 (0.243)	0.07 (0.202)	-0.51 (0.162)	
95% CI [2]	-0.96, 0.47	-0.79, 0.19	-0.33, 0.47	-0.83, -0.19	
Difference (95% CI) in CFB [2]		-0.06 (-0.82, 0.70)		-0.58 (-1.01, -0.15)	
p-value [3]		0.875		0.008	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	31	45	78	
Mean (StdDev)	1.2 (1.21)	0.6 (0.89)	1.2 (1.28)	1.1 (1.33)	
Median	1.0	0.0	1.0	1.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C5D1 CFB					
n	14	28	45	77	
LS Mean (StdErr) [2]	0.13 (0.312)	-0.38 (0.221)	-0.11 (0.182)	-0.59 (0.151)	
95% CI [2]	-0.51, 0.76	-0.83, 0.06	-0.47, 0.25	-0.89, -0.29	
Difference (95% CI) in CFB [2]		-0.51 (-1.20, 0.18)		-0.49 (-0.89, -0.09)	
p-value [3]		0.140		0.018	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	13	32	45	79	
Mean (StdDev)	1.2 (0.99)	0.8 (1.09)	1.2 (1.32)	1.0 (1.25)	
Median	1.0	0.0	1.0	0.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C6D1 CFB					
n	12	29	45	78	
LS Mean (StdErr) [2]	0.07 (0.342)	-0.25 (0.229)	-0.08 (0.187)	-0.64 (0.155)	
95% CI [2]	-0.63, 0.76	-0.72, 0.21	-0.45, 0.29	-0.95, -0.34	
Difference (95% CI) in CFB [2]		-0.32 (-1.07, 0.42)		-0.56 (-0.98, -0.15)	
p-value [3]		0.389		0.008	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	14	34	44	77	
Mean (StdDev)	1.1 (1.00)	0.7 (1.14)	1.2 (1.26)	1.0 (1.30)	
Median	1.0	0.0	1.0	0.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C7D1 CFB					
n	13	31	44	76	
LS Mean (StdErr) [2]	0.19 (0.319)	-0.21 (0.209)	-0.06 (0.190)	-0.50 (0.156)	
95% CI [2]	-0.45, 0.84	-0.63, 0.21	-0.44, 0.31	-0.81, -0.19	
Difference (95% CI) in CFB [2]		-0.41 (-1.10, 0.29)		-0.43 (-0.84, -0.03)	
Hedges'G (95% CI) in CFB		-0.34 (-1.03, 0.31)		-0.33 (-0.71, 0.05)	
p-value [3]		0.246		0.038	
					0.924

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	14	32	51	87	
Mean (StdDev)	2.1 (1.03)	1.6 (0.98)	2.0 (1.15)	2.1 (1.37)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	14	33	51	86	
Mean (StdDev)	1.6 (1.34)	1.2 (0.98)	1.5 (1.24)	1.6 (1.34)	
Median	2.0	1.0	1.0	1.5	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C2D1 CFB					
n	13	31	50	85	
LS Mean (StdErr) [2]	-0.34 (0.272)	-0.46 (0.180)	-0.57 (0.176)	-0.67 (0.150)	
95% CI [2]	-0.89, 0.21	-0.82, -0.09	-0.92, -0.22	-0.97, -0.38	
Difference (95% CI) in CFB [2]		-0.12 (-0.72, 0.48)		-0.10 (-0.49, 0.28)	
p-value [3]		0.687		0.598	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	28	48	81	
Mean (StdDev)	1.7 (1.35)	1.0 (0.92)	1.5 (1.05)	1.5 (1.18)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C3D1 CFB					
n	14	28	47	81	
LS Mean (StdErr) [2]	-0.39 (0.295)	-0.52 (0.207)	-0.43 (0.171)	-0.67 (0.141)	
95% CI [2]	-0.99, 0.21	-0.94, -0.10	-0.77, -0.09	-0.95, -0.39	
Difference (95% CI) in CFB [2]		-0.13 (-0.79, 0.52)		-0.24 (-0.61, 0.14)	
p-value [3]		0.686		0.211	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	13	30	43	83	
Mean (StdDev)	1.4 (1.33)	1.0 (0.91)	1.6 (1.24)	1.5 (1.29)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C4D1 CFB					
n	12	29	42	82	
LS Mean (StdErr) [2]	-0.62 (0.321)	-0.66 (0.222)	-0.28 (0.207)	-0.69 (0.166)	
95% CI [2]	-1.27, 0.03	-1.11, -0.21	-0.69, 0.12	-1.02, -0.37	
Difference (95% CI) in CFB [2]		-0.04 (-0.74, 0.66)		-0.41 (-0.85, 0.03)	
p-value [3]		0.908		0.069	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	31	45	78	
Mean (StdDev)	1.5 (1.46)	0.8 (0.87)	1.5 (1.27)	1.3 (1.27)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C5D1 CFB					
n	14	28	45	77	
LS Mean (StdErr) [2]	-0.52 (0.318)	-0.66 (0.225)	-0.35 (0.192)	-0.86 (0.159)	
95% CI [2]	-1.16, 0.12	-1.12, -0.21	-0.73, 0.03	-1.18, -0.55	
Difference (95% CI) in CFB [2]		-0.14 (-0.84, 0.56)		-0.52 (-0.94, -0.09)	
p-value [3]		0.683		0.017	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	13	32	45	79	
Mean (StdDev)	1.8 (1.42)	0.8 (0.83)	1.5 (1.25)	1.1 (1.22)	
Median	2.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C6D1 CFB					
n	12	29	45	78	
LS Mean (StdErr) [2]	-0.20 (0.314)	-0.82 (0.210)	-0.37 (0.203)	-1.17 (0.168)	
95% CI [2]	-0.83, 0.44	-1.25, -0.40	-0.77, 0.03	-1.51, -0.84	
Difference (95% CI) in CFB [2]		-0.63 (-1.31, 0.06)		-0.80 (-1.25, -0.35)	
p-value [3]		0.072		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	14	34	44	77	
Mean (StdDev)	1.7 (1.38)	0.8 (0.88)	1.5 (1.35)	1.3 (1.35)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C7D1 CFB					
n	13	31	44	76	
LS Mean (StdErr) [2]	-0.34 (0.316)	-0.79 (0.207)	-0.24 (0.238)	-0.75 (0.197)	
95% CI [2]	-0.98, 0.30	-1.21, -0.37	-0.71, 0.23	-1.14, -0.36	
Difference (95% CI) in CFB [2]		-0.45 (-1.14, 0.24)		-0.51 (-1.02, 0.00)	
Hedges'G (95% CI) in CFB		-0.39 (-1.08, 0.27)		-0.30 (-0.69, 0.07)	
p-value [3]		0.192		0.052	
					0.891

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	14	32	51	87	
Mean (StdDev)	2.1 (0.77)	2.2 (1.15)	2.4 (1.06)	2.4 (1.21)	
Median	2.0	2.0	2.0	3.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	14	33	51	86	
Mean (StdDev)	1.8 (1.12)	1.5 (0.97)	1.8 (1.14)	1.8 (1.40)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	13	31	50	85	
LS Mean (StdErr) [2]	-0.20 (0.266)	-0.72 (0.176)	-0.53 (0.176)	-0.55 (0.150)	
95% CI [2]	-0.74, 0.34	-1.07, -0.36	-0.87, -0.18	-0.84, -0.25	
Difference (95% CI) in CFB [2]		-0.52 (-1.10, 0.07)		-0.02 (-0.41, 0.36)	
p-value [3]		0.081		0.914	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	28	48	81	
Mean (StdDev)	1.7 (1.22)	1.4 (1.13)	1.9 (1.09)	1.5 (1.13)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	14	28	47	81	
LS Mean (StdErr) [2]	-0.33 (0.274)	-0.80 (0.193)	-0.47 (0.192)	-0.85 (0.158)	
95% CI [2]	-0.88, 0.23	-1.19, -0.41	-0.85, -0.09	-1.16, -0.54	
Difference (95% CI) in CFB [2]		-0.48 (-1.08, 0.13)		-0.38 (-0.80, 0.03)	
p-value [3]		0.121		0.072	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	13	30	43	82	
Mean (StdDev)	1.7 (1.03)	1.5 (1.14)	1.9 (1.17)	1.5 (1.31)	
Median	2.0	1.5	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C4D1 CFB					
n	12	29	42	81	
LS Mean (StdErr) [2]	-0.55 (0.327)	-0.87 (0.226)	-0.56 (0.206)	-0.99 (0.165)	
95% CI [2]	-1.21, 0.11	-1.32, -0.41	-0.97, -0.15	-1.31, -0.66	
Difference (95% CI) in CFB [2]		-0.31 (-1.02, 0.40)		-0.43 (-0.87, 0.01)	
p-value [3]		0.376		0.057	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	31	45	78	
Mean (StdDev)	1.7 (1.35)	1.1 (0.88)	1.6 (1.33)	1.5 (1.34)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C5D1 CFB					
n	14	28	45	77	
LS Mean (StdErr) [2]	-0.53 (0.308)	-1.11 (0.218)	-0.67 (0.213)	-0.94 (0.177)	
95% CI [2]	-1.16, 0.09	-1.55, -0.67	-1.10, -0.25	-1.29, -0.59	
Difference (95% CI) in CFB [2]		-0.58 (-1.26, 0.10)		-0.26 (-0.73, 0.20)	
p-value [3]		0.092		0.268	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	13	32	45	79	
Mean (StdDev)	1.8 (1.09)	1.3 (1.08)	1.7 (1.29)	1.4 (1.32)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C6D1 CFB					
n	12	29	45	78	
LS Mean (StdErr) [2]	-0.48 (0.344)	-1.05 (0.230)	-0.57 (0.210)	-1.06 (0.174)	
95% CI [2]	-1.18, 0.22	-1.52, -0.58	-0.98, -0.15	-1.41, -0.72	
Difference (95% CI) in CFB [2]		-0.57 (-1.32, 0.18)		-0.50 (-0.96, -0.03)	
p-value [3]		0.133		0.037	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	14	34	44	77	
Mean (StdDev)	1.6 (1.28)	1.2 (1.06)	1.5 (1.23)	1.4 (1.33)	
Median	1.5	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	13	31	44	76	
LS Mean (StdErr) [2]	-0.58 (0.355)	-1.10 (0.233)	-0.55 (0.212)	-0.72 (0.175)	
95% CI [2]	-1.29, 0.14	-1.57, -0.63	-0.97, -0.13	-1.07, -0.37	
Difference (95% CI) in CFB [2]		-0.52 (-1.30, 0.25)		-0.17 (-0.63, 0.29)	
Hedges'G (95% CI) in CFB		-0.40 (-1.09, 0.25)		-0.11 (-0.49, 0.26)	
p-value [3]		0.179		0.465	
					0.364

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	14	32	51	87	
Mean (StdDev)	2.5 (0.85)	2.7 (0.79)	2.7 (1.21)	2.7 (1.19)	
Median	3.0	3.0	3.0	3.0	
Min, Max	1, 4	1, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	14	33	51	86	
Mean (StdDev)	2.3 (1.14)	2.2 (1.00)	2.3 (1.14)	2.2 (1.26)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	13	31	50	85	
LS Mean (StdErr) [2]	-0.21 (0.233)	-0.49 (0.154)	-0.34 (0.164)	-0.56 (0.140)	
95% CI [2]	-0.68, 0.26	-0.81, -0.18	-0.67, -0.02	-0.84, -0.29	
Difference (95% CI) in CFB [2]		-0.28 (-0.79, 0.23)		-0.22 (-0.58, 0.14)	
p-value [3]		0.270		0.229	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	28	48	82	
Mean (StdDev)	2.2 (1.26)	2.0 (0.88)	2.3 (1.16)	2.1 (1.23)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	14	28	47	81	
LS Mean (StdErr) [2]	-0.51 (0.246)	-0.73 (0.173)	-0.43 (0.175)	-0.57 (0.144)	
95% CI [2]	-1.00, -0.01	-1.08, -0.38	-0.78, -0.08	-0.86, -0.29	
Difference (95% CI) in CFB [2]		-0.23 (-0.77, 0.32)		-0.14 (-0.52, 0.24)	
p-value [3]		0.401		0.467	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	13	30	43	83	
Mean (StdDev)	2.5 (1.13)	2.1 (0.97)	2.3 (1.15)	2.0 (1.23)	
Median	3.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	12	29	42	82	
LS Mean (StdErr) [2]	-0.14 (0.279)	-0.59 (0.193)	-0.30 (0.204)	-0.69 (0.163)	
95% CI [2]	-0.70, 0.43	-0.98, -0.20	-0.70, 0.10	-1.01, -0.37	
Difference (95% CI) in CFB [2]		-0.45 (-1.05, 0.16)		-0.39 (-0.82, 0.05)	
p-value [3]		0.140		0.079	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	31	45	78	
Mean (StdDev)	2.2 (1.26)	2.0 (0.87)	2.3 (1.08)	2.1 (1.23)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	14	28	45	77	
LS Mean (StdErr) [2]	-0.53 (0.304)	-0.85 (0.215)	-0.29 (0.206)	-0.64 (0.171)	
95% CI [2]	-1.15, 0.08	-1.29, -0.42	-0.70, 0.11	-0.98, -0.30	
Difference (95% CI) in CFB [2]		-0.32 (-0.99, 0.35)		-0.35 (-0.80, 0.11)	
p-value [3]		0.335		0.131	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	13	32	45	79	
Mean (StdDev)	2.3 (1.38)	1.9 (0.88)	2.4 (1.21)	1.8 (1.24)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	12	29	45	78	
LS Mean (StdErr) [2]	-0.20 (0.271)	-0.88 (0.181)	-0.27 (0.213)	-0.83 (0.177)	
95% CI [2]	-0.75, 0.35	-1.25, -0.52	-0.70, 0.15	-1.18, -0.48	
Difference (95% CI) in CFB [2]		-0.68 (-1.27, -0.09)		-0.55 (-1.02, -0.08)	
p-value [3]		0.025		0.021	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	14	34	44	77	
Mean (StdDev)	2.4 (1.28)	1.9 (0.87)	2.2 (1.24)	1.8 (1.27)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	13	31	44	76	
LS Mean (StdErr) [2]	-0.20 (0.254)	-0.80 (0.166)	-0.21 (0.214)	-0.75 (0.176)	
95% CI [2]	-0.71, 0.32	-1.14, -0.47	-0.63, 0.21	-1.10, -0.40	
Difference (95% CI) in CFB [2]		-0.61 (-1.16, -0.05)		-0.54 (-1.00, -0.08)	
Hedges'G (95% CI) in CFB		-0.64 (-1.36, 0.00)		-0.36 (-0.75, 0.01)	
p-value [3]		0.033		0.021	
					0.799

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	14	32	51	87	
Mean (StdDev)	2.1 (1.56)	1.8 (1.02)	2.3 (1.29)	2.1 (1.40)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	14	33	51	86	
Mean (StdDev)	1.9 (1.41)	1.6 (0.94)	2.0 (1.26)	1.7 (1.44)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C2D1 CFB					
n	13	31	50	85	
LS Mean (StdErr) [2]	0.06 (0.249)	-0.09 (0.165)	-0.32 (0.164)	-0.42 (0.140)	
95% CI [2]	-0.44, 0.57	-0.42, 0.24	-0.65, 0.00	-0.70, -0.15	
Difference (95% CI) in CFB [2]		-0.15 (-0.70, 0.39)		-0.10 (-0.46, 0.26)	
p-value [3]		0.574		0.571	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	28	47	82	
Mean (StdDev)	1.7 (1.44)	1.3 (0.90)	1.8 (1.22)	1.6 (1.32)	
Median	2.0	1.5	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C3D1 CFB					
n	14	28	46	81	
LS Mean (StdErr) [2]	-0.17 (0.312)	-0.37 (0.219)	-0.51 (0.173)	-0.52 (0.142)	
95% CI [2]	-0.80, 0.46	-0.82, 0.07	-0.85, -0.17	-0.80, -0.23	
Difference (95% CI) in CFB [2]		-0.20 (-0.89, 0.49)		-0.00 (-0.38, 0.37)	
p-value [3]		0.555		0.985	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	13	30	43	83	
Mean (StdDev)	1.8 (1.52)	1.5 (1.04)	1.8 (1.32)	1.6 (1.41)	
Median	2.0	1.5	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	12	29	42	82	
LS Mean (StdErr) [2]	-0.07 (0.303)	-0.29 (0.210)	-0.58 (0.207)	-0.62 (0.166)	
95% CI [2]	-0.68, 0.55	-0.71, 0.14	-0.99, -0.17	-0.95, -0.29	
Difference (95% CI) in CFB [2]		-0.22 (-0.88, 0.44)		-0.04 (-0.48, 0.40)	
p-value [3]		0.505		0.870	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	31	45	78	
Mean (StdDev)	1.6 (1.40)	1.1 (0.98)	1.8 (1.33)	1.5 (1.35)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	14	28	45	77	
LS Mean (StdErr) [2]	-0.38 (0.359)	-0.56 (0.254)	-0.55 (0.206)	-0.80 (0.171)	
95% CI [2]	-1.10, 0.35	-1.07, -0.04	-0.96, -0.14	-1.13, -0.46	
Difference (95% CI) in CFB [2]		-0.18 (-0.97, 0.61)		-0.25 (-0.70, 0.20)	
p-value [3]		0.651		0.279	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	13	32	45	79	
Mean (StdDev)	2.0 (1.47)	1.2 (1.04)	1.9 (1.40)	1.4 (1.27)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	12	29	45	78	
LS Mean (StdErr) [2]	-0.02 (0.353)	-0.64 (0.236)	-0.32 (0.209)	-0.77 (0.173)	
95% CI [2]	-0.73, 0.70	-1.12, -0.16	-0.74, 0.09	-1.11, -0.43	
Difference (95% CI) in CFB [2]		-0.62 (-1.39, 0.15)		-0.45 (-0.91, 0.01)	
p-value [3]		0.110		0.058	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	14	34	44	77	
Mean (StdDev)	1.9 (1.46)	1.1 (1.07)	1.8 (1.35)	1.3 (1.40)	
Median	1.5	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	13	31	44	76	
LS Mean (StdErr) [2]	-0.18 (0.370)	-0.54 (0.242)	-0.38 (0.189)	-0.73 (0.156)	
95% CI [2]	-0.93, 0.57	-1.03, -0.05	-0.75, -0.01	-1.03, -0.42	
Difference (95% CI) in CFB [2]		-0.36 (-1.17, 0.44)		-0.35 (-0.75, 0.06)	
Hedges'G (95% CI) in CFB		-0.26 (-0.95, 0.39)		-0.26 (-0.64, 0.11)	
p-value [3]		0.369		0.094	
					0.953

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	14	32	51	87	
Mean (StdDev)	2.4 (1.01)	2.3 (1.08)	2.5 (1.03)	2.6 (1.06)	
Median	2.0	2.0	3.0	3.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	14	33	51	86	
Mean (StdDev)	2.1 (1.00)	1.7 (0.89)	1.9 (1.08)	1.9 (1.22)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 3	0, 4	0, 4	
C2D1 CFB					
n	13	31	50	85	
LS Mean (StdErr) [2]	-0.12 (0.238)	-0.65 (0.157)	-0.53 (0.185)	-0.73 (0.158)	
95% CI [2]	-0.60, 0.36	-0.96, -0.33	-0.90, -0.17	-1.05, -0.42	
Difference (95% CI) in CFB [2]		-0.52 (-1.05, -0.00)		-0.20 (-0.61, 0.20)	
p-value [3]		0.050		0.330	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	27	48	82	
Mean (StdDev)	2.1 (1.28)	1.6 (0.93)	2.0 (1.07)	1.8 (1.11)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	14	27	47	81	
LS Mean (StdErr) [2]	-0.36 (0.398)	-0.78 (0.281)	-0.49 (0.181)	-0.85 (0.149)	
95% CI [2]	-1.17, 0.44	-1.35, -0.21	-0.85, -0.13	-1.15, -0.56	
Difference (95% CI) in CFB [2]		-0.42 (-1.30, 0.47)		-0.37 (-0.76, 0.03)	
p-value [3]		0.348		0.069	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	13	30	43	83	
Mean (StdDev)	2.3 (1.11)	1.5 (1.07)	1.8 (1.10)	1.7 (1.17)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	12	29	42	82	
LS Mean (StdErr) [2]	-0.14 (0.374)	-0.83 (0.258)	-0.69 (0.193)	-0.92 (0.155)	
95% CI [2]	-0.89, 0.62	-1.35, -0.31	-1.07, -0.31	-1.23, -0.62	
Difference (95% CI) in CFB [2]		-0.69 (-1.50, 0.12)		-0.23 (-0.65, 0.18)	
p-value [3]		0.092		0.263	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	31	45	78	
Mean (StdDev)	1.8 (1.32)	1.3 (0.94)	1.8 (1.13)	1.6 (1.21)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	14	28	45	77	
LS Mean (StdErr) [2]	-0.73 (0.424)	-1.01 (0.300)	-0.60 (0.198)	-1.08 (0.164)	
95% CI [2]	-1.59, 0.13	-1.61, -0.40	-0.99, -0.21	-1.40, -0.75	
Difference (95% CI) in CFB [2]		-0.28 (-1.21, 0.65)		-0.48 (-0.91, -0.04)	
p-value [3]		0.550		0.031	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	13	32	45	79	
Mean (StdDev)	1.9 (0.95)	1.4 (1.04)	1.9 (1.21)	1.5 (1.20)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	12	29	45	78	
LS Mean (StdErr) [2]	-0.53 (0.352)	-1.15 (0.236)	-0.51 (0.205)	-1.10 (0.170)	
95% CI [2]	-1.24, 0.19	-1.63, -0.67	-0.92, -0.11	-1.43, -0.76	
Difference (95% CI) in CFB [2]		-0.62 (-1.39, 0.15)		-0.59 (-1.04, -0.14)	
p-value [3]		0.110		0.011	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	14	34	44	77	
Mean (StdDev)	2.1 (1.17)	1.4 (1.04)	1.8 (1.30)	1.6 (1.37)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	13	31	44	76	
LS Mean (StdErr) [2]	-0.18 (0.410)	-0.98 (0.269)	-0.51 (0.233)	-1.00 (0.192)	
95% CI [2]	-1.01, 0.65	-1.53, -0.44	-0.97, -0.05	-1.38, -0.62	
Difference (95% CI) in CFB [2]		-0.80 (-1.69, 0.09)		-0.49 (-0.99, 0.01)	
Hedges'G (95% CI) in CFB		-0.53 (-1.23, 0.12)		-0.30 (-0.68, 0.07)	
p-value [3]		0.077		0.055	
					0.505

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	14	32	50	87	
Mean (StdDev)	2.0 (1.47)	2.0 (1.09)	2.1 (1.21)	2.3 (1.20)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	14	33	51	86	
Mean (StdDev)	1.6 (1.34)	1.8 (1.03)	1.9 (1.21)	1.8 (1.23)	
Median	1.5	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	13	31	49	85	
LS Mean (StdErr) [2]	-0.15 (0.260)	-0.25 (0.172)	-0.16 (0.177)	-0.53 (0.150)	
95% CI [2]	-0.68, 0.37	-0.60, 0.10	-0.51, 0.19	-0.83, -0.23	
Difference (95% CI) in CFB [2]		-0.10 (-0.67, 0.47)		-0.37 (-0.76, 0.02)	
p-value [3]		0.736		0.062	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	28	48	82	
Mean (StdDev)	1.8 (1.26)	1.5 (1.11)	1.8 (1.19)	1.7 (1.10)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	14	28	46	81	
LS Mean (StdErr) [2]	-0.08 (0.311)	-0.53 (0.219)	-0.17 (0.168)	-0.59 (0.138)	
95% CI [2]	-0.71, 0.55	-0.97, -0.09	-0.50, 0.16	-0.86, -0.31	
Difference (95% CI) in CFB [2]		-0.45 (-1.13, 0.24)		-0.42 (-0.78, -0.05)	
p-value [3]		0.199		0.027	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	13	30	43	83	
Mean (StdDev)	1.7 (1.38)	1.4 (1.19)	1.8 (1.21)	1.7 (1.26)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	12	29	41	82	
LS Mean (StdErr) [2]	-0.10 (0.303)	-0.60 (0.209)	-0.23 (0.211)	-0.60 (0.168)	
95% CI [2]	-0.72, 0.51	-1.02, -0.17	-0.64, 0.19	-0.93, -0.27	
Difference (95% CI) in CFB [2]		-0.49 (-1.15, 0.16)		-0.38 (-0.83, 0.07)	
p-value [3]		0.137		0.101	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	31	45	78	
Mean (StdDev)	1.6 (1.18)	1.4 (1.06)	1.7 (1.10)	1.5 (1.19)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	14	28	44	77	
LS Mean (StdErr) [2]	-0.30 (0.334)	-0.53 (0.236)	-0.26 (0.199)	-0.77 (0.165)	
95% CI [2]	-0.98, 0.38	-1.01, -0.05	-0.65, 0.14	-1.10, -0.45	
Difference (95% CI) in CFB [2]		-0.23 (-0.96, 0.50)		-0.51 (-0.95, -0.08)	
p-value [3]		0.530		0.022	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	13	32	45	79	
Mean (StdDev)	1.8 (1.28)	1.4 (1.13)	1.8 (1.20)	1.5 (1.26)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	12	29	44	78	
LS Mean (StdErr) [2]	-0.12 (0.291)	-0.79 (0.195)	-0.23 (0.212)	-0.81 (0.175)	
95% CI [2]	-0.71, 0.47	-1.18, -0.39	-0.65, 0.19	-1.16, -0.47	
Difference (95% CI) in CFB [2]		-0.66 (-1.30, -0.03)		-0.59 (-1.06, -0.12)	
p-value [3]		0.041		0.015	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	14	34	44	77	
Mean (StdDev)	1.7 (1.27)	1.4 (1.08)	1.7 (1.17)	1.6 (1.34)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	13	31	43	76	
LS Mean (StdErr) [2]	-0.15 (0.364)	-0.53 (0.238)	-0.06 (0.217)	-0.57 (0.178)	
95% CI [2]	-0.88, 0.59	-1.01, -0.05	-0.49, 0.37	-0.92, -0.21	
Difference (95% CI) in CFB [2]		-0.38 (-1.17, 0.41)		-0.50 (-0.97, -0.03)	
Hedges'G (95% CI) in CFB		-0.28 (-0.97, 0.37)		-0.33 (-0.72, 0.04)	
p-value [3]		0.340		0.036	
					0.836

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-sex-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	30	49	35	70	
Mean (StdDev)	2.7 (1.26)	2.4 (1.13)	2.8 (1.02)	2.3 (1.07)	
Median	3.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	30	51	35	68	
Mean (StdDev)	2.3 (1.02)	1.6 (0.92)	2.3 (1.05)	1.7 (0.90)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	28	48	35	68	
LS Mean (StdErr) [2]	-0.45 (0.241)	-0.72 (0.201)	-0.35 (0.192)	-0.50 (0.148)	
95% CI [2]	-0.94, 0.03	-1.12, -0.32	-0.73, 0.03	-0.79, -0.20	
Difference (95% CI) in CFB [2]		-0.27 (-0.80, 0.27)		-0.15 (-0.57, 0.27)	
p-value [3]		0.324		0.477	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	29	44	34	66	
Mean (StdDev)	2.1 (1.05)	1.4 (0.84)	2.1 (1.20)	1.6 (0.99)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C3D1 CFB					
n	27	43	34	66	
LS Mean (StdErr) [2]	-0.64 (0.251)	-0.93 (0.211)	-0.58 (0.216)	-0.64 (0.163)	
95% CI [2]	-1.14, -0.14	-1.35, -0.50	-1.01, -0.15	-0.96, -0.31	
Difference (95% CI) in CFB [2]		-0.29 (-0.84, 0.27)		-0.06 (-0.53, 0.41)	
p-value [3]		0.305		0.807	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	22	44	34	69	
Mean (StdDev)	2.4 (1.05)	1.3 (0.94)	2.2 (1.11)	1.5 (1.08)	
Median	2.0	1.0	2.0	1.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	20	43	34	68	
LS Mean (StdErr) [2]	-0.47 (0.290)	-1.16 (0.232)	-0.52 (0.227)	-0.78 (0.171)	
95% CI [2]	-1.05, 0.11	-1.63, -0.70	-0.97, -0.07	-1.12, -0.44	
Difference (95% CI) in CFB [2]		-0.69 (-1.30, -0.09)		-0.26 (-0.75, 0.24)	
p-value [3]		0.024		0.304	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	26	40	34	68	
Mean (StdDev)	2.3 (1.29)	1.3 (0.98)	2.2 (1.13)	1.4 (0.97)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	25	37	34	67	
LS Mean (StdErr) [2]	-0.41 (0.276)	-1.08 (0.238)	-0.39 (0.231)	-0.75 (0.175)	
95% CI [2]	-0.96, 0.14	-1.55, -0.60	-0.85, 0.07	-1.10, -0.40	
Difference (95% CI) in CFB [2]		-0.67 (-1.29, -0.05)		-0.36 (-0.86, 0.14)	
p-value [3]		0.036		0.159	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	24	44	34	67	
Mean (StdDev)	2.0 (1.33)	1.4 (1.01)	2.3 (1.11)	1.5 (1.05)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-0.83 (0.264)	-1.06 (0.219)	-0.41 (0.232)	-0.72 (0.175)	
95% CI [2]	-1.35, -0.30	-1.49, -0.62	-0.87, 0.05	-1.07, -0.38	
Difference (95% CI) in CFB [2]		-0.23 (-0.82, 0.36)		-0.31 (-0.82, 0.19)	
p-value [3]		0.434		0.220	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	24	44	34	67	
Mean (StdDev)	2.3 (1.30)	1.2 (0.82)	2.3 (1.04)	1.4 (1.03)	
Median	3.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C7D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-0.60 (0.289)	-1.11 (0.231)	-0.23 (0.208)	-0.73 (0.157)	
95% CI [2]	-1.18, -0.02	-1.58, -0.65	-0.65, 0.18	-1.04, -0.42	
Difference (95% CI) in CFB [2]		-0.52 (-1.12, 0.09)		-0.49 (-0.95, -0.04)	
Hedges'G (95% CI) in CFB		-0.35 (-0.89, 0.16)		-0.39 (-0.82, 0.02)	
p-value [3]		0.095		0.033	
					0.905

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	30	49	35	70	
Mean (StdDev)	2.7 (1.18)	2.1 (1.22)	2.4 (1.14)	2.2 (1.09)	
Median	3.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	30	51	35	68	
Mean (StdDev)	2.4 (1.16)	1.4 (1.14)	2.1 (1.08)	1.5 (0.87)	
Median	2.5	1.0	2.0	1.5	
Min, Max	0, 4	0, 4	0, 4	0, 3	
C2D1 CFB					
n	28	48	35	68	
LS Mean (StdErr) [2]	-0.11 (0.272)	-0.52 (0.227)	-0.22 (0.199)	-0.60 (0.154)	
95% CI [2]	-0.66, 0.43	-0.97, -0.06	-0.62, 0.17	-0.90, -0.29	
Difference (95% CI) in CFB [2]		-0.40 (-1.01, 0.20)		-0.37 (-0.81, 0.06)	
p-value [3]		0.185		0.090	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	29	44	34	66	
Mean (StdDev)	2.2 (1.26)	1.4 (1.01)	2.1 (1.22)	1.5 (1.00)	
Median	2.0	1.0	2.0	1.5	
Min, Max	0, 4	0, 4	0, 4	0, 3	
C3D1 CFB					
n	27	43	34	66	
LS Mean (StdErr) [2]	-0.38 (0.275)	-0.59 (0.232)	-0.29 (0.227)	-0.64 (0.171)	
95% CI [2]	-0.93, 0.17	-1.05, -0.13	-0.74, 0.16	-0.98, -0.31	
Difference (95% CI) in CFB [2]		-0.21 (-0.82, 0.40)		-0.35 (-0.85, 0.14)	
p-value [3]		0.487		0.160	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	22	44	34	69	
Mean (StdDev)	2.3 (0.99)	1.2 (1.01)	2.1 (1.11)	1.4 (1.06)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	20	43	34	68	
LS Mean (StdErr) [2]	-0.41 (0.291)	-0.97 (0.233)	-0.13 (0.227)	-0.61 (0.171)	
95% CI [2]	-1.00, 0.17	-1.44, -0.51	-0.58, 0.32	-0.95, -0.27	
Difference (95% CI) in CFB [2]		-0.56 (-1.16, 0.04)		-0.48 (-0.98, 0.01)	
p-value [3]		0.068		0.055	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	26	40	34	68	
Mean (StdDev)	2.2 (1.41)	1.3 (0.95)	2.1 (1.18)	1.4 (1.00)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	25	37	34	67	
LS Mean (StdErr) [2]	-0.29 (0.287)	-0.67 (0.247)	-0.17 (0.225)	-0.58 (0.171)	
95% CI [2]	-0.87, 0.28	-1.17, -0.18	-0.62, 0.28	-0.92, -0.24	
Difference (95% CI) in CFB [2]		-0.38 (-1.02, 0.26)		-0.41 (-0.90, 0.08)	
p-value [3]		0.243		0.097	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	24	44	34	67	
Mean (StdDev)	2.3 (1.20)	1.3 (0.93)	2.0 (1.15)	1.6 (1.17)	
Median	2.5	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-0.03 (0.278)	-0.71 (0.230)	-0.26 (0.235)	-0.51 (0.177)	
95% CI [2]	-0.58, 0.53	-1.17, -0.24	-0.73, 0.21	-0.86, -0.16	
Difference (95% CI) in CFB [2]		-0.68 (-1.30, -0.06)		-0.25 (-0.76, 0.26)	
p-value [3]		0.031		0.337	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	24	44	34	67	
Mean (StdDev)	2.1 (1.30)	1.3 (0.94)	2.1 (1.13)	1.5 (1.17)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-0.27 (0.308)	-0.62 (0.246)	-0.00 (0.233)	-0.46 (0.176)	
95% CI [2]	-0.88, 0.35	-1.11, -0.13	-0.46, 0.46	-0.80, -0.11	
Difference (95% CI) in CFB [2]		-0.35 (-1.00, 0.29)		-0.45 (-0.96, 0.05)	
Hedges'G (95% CI) in CFB		-0.23 (-0.76, 0.29)		-0.32 (-0.75, 0.09)	
p-value [3]		0.279		0.079	
					0.798

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	30	49	35	70	
Mean (StdDev)	2.3 (1.02)	2.4 (1.00)	2.3 (1.24)	2.3 (1.14)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	1, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	30	51	35	68	
Mean (StdDev)	2.1 (1.04)	1.6 (1.05)	2.0 (1.15)	2.0 (1.07)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	28	48	35	68	
LS Mean (StdErr) [2]	-0.34 (0.220)	-0.82 (0.183)	-0.03 (0.184)	-0.13 (0.142)	
95% CI [2]	-0.78, 0.10	-1.18, -0.45	-0.39, 0.34	-0.41, 0.15	
Difference (95% CI) in CFB [2]		-0.48 (-0.96, 0.01)		-0.10 (-0.50, 0.30)	
p-value [3]		0.054		0.617	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	29	44	34	66	
Mean (StdDev)	2.1 (0.92)	1.8 (1.15)	1.9 (1.12)	1.7 (1.07)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	27	43	34	66	
LS Mean (StdErr) [2]	-0.11 (0.269)	-0.47 (0.226)	-0.18 (0.203)	-0.43 (0.153)	
95% CI [2]	-0.65, 0.43	-0.92, -0.02	-0.59, 0.22	-0.73, -0.12	
Difference (95% CI) in CFB [2]		-0.36 (-0.95, 0.24)		-0.24 (-0.69, 0.20)	
p-value [3]		0.234		0.279	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	22	44	34	69	
Mean (StdDev)	2.3 (1.12)	1.7 (0.95)	2.0 (1.15)	1.8 (1.08)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	20	43	34	68	
LS Mean (StdErr) [2]	-0.15 (0.292)	-0.64 (0.234)	-0.10 (0.218)	-0.45 (0.164)	
95% CI [2]	-0.73, 0.44	-1.11, -0.18	-0.53, 0.34	-0.77, -0.12	
Difference (95% CI) in CFB [2]		-0.50 (-1.10, 0.11)		-0.35 (-0.82, 0.12)	
p-value [3]		0.106		0.144	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	26	40	34	68	
Mean (StdDev)	2.0 (1.25)	1.8 (1.08)	2.1 (1.24)	1.8 (1.08)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	25	37	34	67	
LS Mean (StdErr) [2]	-0.43 (0.261)	-0.66 (0.225)	0.01 (0.240)	-0.44 (0.182)	
95% CI [2]	-0.96, 0.09	-1.11, -0.21	-0.46, 0.49	-0.80, -0.08	
Difference (95% CI) in CFB [2]		-0.23 (-0.82, 0.36)		-0.46 (-0.98, 0.07)	
p-value [3]		0.437		0.087	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	24	44	34	67	
Mean (StdDev)	2.0 (1.30)	1.5 (1.07)	1.8 (1.12)	1.8 (1.17)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-0.14 (0.282)	-0.93 (0.234)	-0.28 (0.221)	-0.35 (0.167)	
95% CI [2]	-0.70, 0.43	-1.40, -0.46	-0.72, 0.15	-0.68, -0.02	
Difference (95% CI) in CFB [2]		-0.79 (-1.42, -0.16)		-0.06 (-0.54, 0.42)	
p-value [3]		0.015		0.798	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	24	44	34	67	
Mean (StdDev)	1.9 (1.26)	1.5 (0.98)	1.9 (1.04)	1.8 (1.18)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C7D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-0.57 (0.282)	-1.10 (0.226)	-0.15 (0.241)	-0.32 (0.182)	
95% CI [2]	-1.13, -0.01	-1.55, -0.65	-0.63, 0.33	-0.68, 0.04	
Difference (95% CI) in CFB [2]		-0.53 (-1.12, 0.07)		-0.17 (-0.70, 0.35)	
Hedges'G (95% CI) in CFB		-0.37 (-0.91, 0.14)		-0.12 (-0.54, 0.30)	
p-value [3]		0.080		0.519	
					0.349

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	30	49	35	70	
Mean (StdDev)	1.9 (1.24)	2.3 (1.23)	2.3 (1.15)	2.0 (1.19)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	30	50	35	68	
Mean (StdDev)	1.6 (1.30)	1.6 (1.11)	1.8 (1.05)	1.5 (1.15)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	28	47	35	68	
LS Mean (StdErr) [2]	-0.29 (0.270)	-0.68 (0.233)	-0.30 (0.203)	-0.40 (0.157)	
95% CI [2]	-0.83, 0.25	-1.15, -0.22	-0.70, 0.10	-0.71, -0.09	
Difference (95% CI) in CFB [2]		-0.39 (-0.99, 0.20)		-0.10 (-0.54, 0.34)	
p-value [3]		0.189		0.656	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	29	44	34	66	
Mean (StdDev)	1.7 (1.33)	1.7 (1.14)	1.8 (1.27)	1.4 (1.15)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	27	43	34	66	
LS Mean (StdErr) [2]	-0.16 (0.302)	-0.60 (0.254)	-0.23 (0.229)	-0.45 (0.173)	
95% CI [2]	-0.77, 0.44	-1.11, -0.09	-0.69, 0.22	-0.80, -0.11	
Difference (95% CI) in CFB [2]		-0.44 (-1.10, 0.23)		-0.22 (-0.72, 0.28)	
p-value [3]		0.196		0.383	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	22	44	34	69	
Mean (StdDev)	1.8 (1.34)	1.7 (1.16)	1.8 (1.15)	1.4 (1.20)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	20	43	34	68	
LS Mean (StdErr) [2]	-0.50 (0.328)	-0.76 (0.263)	-0.29 (0.211)	-0.47 (0.159)	
95% CI [2]	-1.16, 0.16	-1.29, -0.24	-0.70, 0.13	-0.78, -0.15	
Difference (95% CI) in CFB [2]		-0.26 (-0.94, 0.42)		-0.18 (-0.64, 0.28)	
p-value [3]		0.442		0.437	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	26	40	34	68	
Mean (StdDev)	1.6 (1.17)	1.6 (1.24)	2.0 (1.03)	1.3 (1.11)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	25	37	34	67	
LS Mean (StdErr) [2]	-0.21 (0.283)	-0.82 (0.243)	-0.11 (0.239)	-0.55 (0.182)	
95% CI [2]	-0.77, 0.36	-1.31, -0.33	-0.59, 0.36	-0.91, -0.19	
Difference (95% CI) in CFB [2]		-0.61 (-1.25, 0.02)		-0.44 (-0.96, 0.08)	
p-value [3]		0.059		0.098	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	24	44	34	67	
Mean (StdDev)	1.6 (1.28)	1.2 (1.00)	1.9 (1.13)	1.5 (1.22)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-0.31 (0.278)	-1.12 (0.231)	-0.12 (0.228)	-0.31 (0.172)	
95% CI [2]	-0.86, 0.25	-1.58, -0.66	-0.58, 0.33	-0.65, 0.03	
Difference (95% CI) in CFB [2]		-0.81 (-1.43, -0.19)		-0.18 (-0.68, 0.31)	
p-value [3]		0.011		0.465	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	24	44	34	67	
Mean (StdDev)	1.5 (1.10)	1.3 (1.19)	1.9 (1.08)	1.5 (1.27)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C7D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-0.09 (0.326)	-0.86 (0.261)	-0.18 (0.218)	-0.29 (0.165)	
95% CI [2]	-0.74, 0.56	-1.38, -0.33	-0.61, 0.26	-0.62, 0.03	
Difference (95% CI) in CFB [2]		-0.77 (-1.45, -0.08)		-0.12 (-0.59, 0.36)	
Hedges'G (95% CI) in CFB		-0.46 (-1.01, 0.05)		-0.09 (-0.51, 0.33)	
p-value [3]		0.029		0.627	
					0.102

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	30	49	35	70	
Mean (StdDev)	3.0 (1.02)	3.2 (0.90)	3.3 (0.82)	3.3 (0.85)	
Median	3.0	3.0	3.0	3.0	
Min, Max	1, 4	1, 4	2, 4	1, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	30	51	35	68	
Mean (StdDev)	2.7 (1.05)	2.6 (1.13)	2.9 (0.88)	2.8 (1.04)	
Median	3.0	3.0	3.0	3.0	
Min, Max	1, 4	0, 4	1, 4	1, 4	
C2D1 CFB					
n	28	48	35	68	
LS Mean (StdErr) [2]	-0.34 (0.220)	-0.67 (0.183)	-0.39 (0.171)	-0.47 (0.132)	
95% CI [2]	-0.78, 0.10	-1.03, -0.30	-0.73, -0.05	-0.73, -0.20	
Difference (95% CI) in CFB [2]		-0.33 (-0.81, 0.16)		-0.07 (-0.45, 0.30)	
p-value [3]		0.184		0.698	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	29	44	34	66	
Mean (StdDev)	2.7 (1.32)	2.5 (1.09)	2.7 (0.91)	2.6 (1.10)	
Median	3.0	3.0	3.0	3.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C3D1 CFB					
n	27	43	34	66	
LS Mean (StdErr) [2]	-0.34 (0.244)	-0.82 (0.205)	-0.52 (0.204)	-0.64 (0.154)	
95% CI [2]	-0.83, 0.15	-1.23, -0.41	-0.92, -0.11	-0.95, -0.34	
Difference (95% CI) in CFB [2]		-0.49 (-1.02, 0.05)		-0.12 (-0.57, 0.32)	
p-value [3]		0.076		0.583	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	22	44	34	69	
Mean (StdDev)	2.8 (1.22)	2.2 (1.05)	2.7 (1.08)	2.7 (1.12)	
Median	3.0	2.0	3.0	3.0	
Min, Max	1, 4	0, 4	1, 4	0, 4	
C4D1 CFB					
n	20	43	34	68	
LS Mean (StdErr) [2]	-0.51 (0.228)	-1.08 (0.183)	-0.45 (0.229)	-0.52 (0.172)	
95% CI [2]	-0.97, -0.06	-1.45, -0.72	-0.91, 0.00	-0.86, -0.18	
Difference (95% CI) in CFB [2]		-0.57 (-1.04, -0.10)		-0.06 (-0.56, 0.43)	
p-value [3]		0.019		0.799	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	26	40	34	68	
Mean (StdDev)	2.5 (1.42)	2.3 (1.15)	2.9 (1.02)	2.5 (1.15)	
Median	3.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	25	37	34	67	
LS Mean (StdErr) [2]	-0.71 (0.255)	-1.09 (0.219)	-0.24 (0.216)	-0.65 (0.164)	
95% CI [2]	-1.22, -0.20	-1.53, -0.65	-0.67, 0.19	-0.97, -0.32	
Difference (95% CI) in CFB [2]		-0.38 (-0.95, 0.19)		-0.41 (-0.88, 0.06)	
p-value [3]		0.191		0.088	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	24	44	34	67	
Mean (StdDev)	2.6 (1.28)	2.0 (1.11)	2.6 (0.98)	2.5 (1.20)	
Median	2.5	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C6D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-0.67 (0.257)	-1.35 (0.213)	-0.52 (0.224)	-0.62 (0.169)	
95% CI [2]	-1.18, -0.15	-1.77, -0.92	-0.96, -0.07	-0.95, -0.28	
Difference (95% CI) in CFB [2]		-0.68 (-1.25, -0.11)		-0.10 (-0.59, 0.39)	
p-value [3]		0.020		0.678	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	24	44	34	67	
Mean (StdDev)	2.4 (1.28)	2.1 (1.04)	2.8 (0.92)	2.6 (1.15)	
Median	2.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C7D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-0.78 (0.262)	-1.17 (0.209)	-0.38 (0.215)	-0.59 (0.162)	
95% CI [2]	-1.31, -0.26	-1.59, -0.76	-0.81, 0.05	-0.91, -0.26	
Difference (95% CI) in CFB [2]		-0.39 (-0.94, 0.16)		-0.21 (-0.68, 0.26)	
Hedges'G (95% CI) in CFB		-0.30 (-0.83, 0.22)		-0.16 (-0.58, 0.26)	
p-value [3]		0.160		0.383	
					0.557

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	30	49	35	70	
Mean (StdDev)	2.0 (1.17)	2.2 (0.98)	2.3 (1.09)	2.2 (1.09)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	30	51	35	68	
Mean (StdDev)	2.1 (1.23)	1.8 (0.94)	1.9 (0.97)	1.9 (1.02)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	28	48	35	68	
LS Mean (StdErr) [2]	0.13 (0.216)	-0.46 (0.180)	-0.37 (0.159)	-0.19 (0.123)	
95% CI [2]	-0.30, 0.56	-0.81, -0.10	-0.68, -0.05	-0.43, 0.06	
Difference (95% CI) in CFB [2]		-0.59 (-1.06, -0.11)		0.18 (-0.17, 0.53)	
p-value [3]		0.017		0.306	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	29	44	34	66	
Mean (StdDev)	1.8 (1.23)	1.8 (0.81)	1.9 (1.03)	1.6 (1.07)	
Median	2.0	2.0	2.0	1.5	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	27	43	34	66	
LS Mean (StdErr) [2]	-0.21 (0.227)	-0.64 (0.191)	-0.29 (0.207)	-0.46 (0.156)	
95% CI [2]	-0.66, 0.25	-1.02, -0.26	-0.71, 0.12	-0.77, -0.15	
Difference (95% CI) in CFB [2]		-0.44 (-0.94, 0.07)		-0.17 (-0.62, 0.28)	
p-value [3]		0.088		0.458	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	22	44	34	69	
Mean (StdDev)	1.8 (1.26)	1.8 (0.97)	2.1 (1.15)	1.8 (1.27)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	20	43	34	68	
LS Mean (StdErr) [2]	-0.17 (0.274)	-0.39 (0.219)	-0.18 (0.216)	-0.31 (0.163)	
95% CI [2]	-0.72, 0.37	-0.83, 0.05	-0.61, 0.25	-0.63, 0.01	
Difference (95% CI) in CFB [2]		-0.21 (-0.78, 0.35)		-0.14 (-0.61, 0.33)	
p-value [3]		0.456		0.567	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	26	40	34	68	
Mean (StdDev)	2.0 (1.31)	1.8 (1.00)	1.9 (1.20)	1.7 (1.19)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	25	37	34	67	
LS Mean (StdErr) [2]	-0.10 (0.234)	-0.36 (0.201)	-0.32 (0.208)	-0.45 (0.157)	
95% CI [2]	-0.57, 0.37	-0.77, 0.04	-0.74, 0.09	-0.76, -0.14	
Difference (95% CI) in CFB [2]		-0.27 (-0.79, 0.26)		-0.13 (-0.58, 0.32)	
p-value [3]		0.315		0.577	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	24	44	34	67	
Mean (StdDev)	2.0 (1.20)	1.6 (1.06)	1.9 (1.02)	1.7 (1.21)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-0.22 (0.245)	-0.68 (0.203)	-0.25 (0.193)	-0.36 (0.146)	
95% CI [2]	-0.71, 0.27	-1.08, -0.27	-0.64, 0.13	-0.65, -0.07	
Difference (95% CI) in CFB [2]		-0.46 (-1.00, 0.09)		-0.11 (-0.53, 0.31)	
p-value [3]		0.097		0.612	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	24	44	34	67	
Mean (StdDev)	1.8 (1.11)	1.6 (1.04)	1.8 (1.09)	1.6 (1.14)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-0.13 (0.241)	-0.52 (0.193)	-0.42 (0.197)	-0.45 (0.149)	
95% CI [2]	-0.61, 0.35	-0.91, -0.13	-0.81, -0.02	-0.75, -0.16	
Difference (95% CI) in CFB [2]		-0.39 (-0.90, 0.12)		-0.04 (-0.47, 0.39)	
Hedges'G (95% CI) in CFB		-0.32 (-0.85, 0.19)		-0.03 (-0.45, 0.39)	
p-value [3]		0.129		0.868	
					0.306

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	30	49	35	70	
Mean (StdDev)	2.5 (1.28)	2.8 (1.25)	2.9 (1.05)	2.8 (1.06)	
Median	3.0	3.0	3.0	3.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	30	50	35	68	
Mean (StdDev)	2.2 (1.30)	2.2 (1.08)	2.4 (0.88)	2.2 (1.12)	
Median	2.5	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C2D1 CFB					
n	28	47	35	68	
LS Mean (StdErr) [2]	-0.24 (0.225)	-0.35 (0.194)	-0.36 (0.158)	-0.50 (0.122)	
95% CI [2]	-0.69, 0.21	-0.74, 0.04	-0.68, -0.05	-0.74, -0.25	
Difference (95% CI) in CFB [2]		-0.11 (-0.61, 0.38)		-0.13 (-0.47, 0.21)	
p-value [3]		0.649		0.450	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	29	44	34	66	
Mean (StdDev)	2.0 (1.27)	2.2 (1.31)	2.4 (1.02)	2.1 (1.16)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	27	43	34	66	
LS Mean (StdErr) [2]	-0.53 (0.287)	-0.57 (0.242)	-0.44 (0.187)	-0.61 (0.141)	
95% CI [2]	-1.10, 0.05	-1.05, -0.09	-0.81, -0.07	-0.89, -0.33	
Difference (95% CI) in CFB [2]		-0.04 (-0.68, 0.59)		-0.16 (-0.57, 0.25)	
p-value [3]		0.894		0.430	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	22	44	34	69	
Mean (StdDev)	2.3 (1.32)	2.2 (1.22)	2.5 (1.05)	2.2 (1.23)	
Median	3.0	2.0	2.5	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	20	43	34	68	
LS Mean (StdErr) [2]	-0.42 (0.352)	-0.75 (0.282)	-0.23 (0.208)	-0.47 (0.157)	
95% CI [2]	-1.13, 0.28	-1.32, -0.19	-0.65, 0.18	-0.78, -0.16	
Difference (95% CI) in CFB [2]		-0.33 (-1.06, 0.40)		-0.23 (-0.69, 0.22)	
p-value [3]		0.370		0.307	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	26	40	34	68	
Mean (StdDev)	2.2 (1.26)	2.2 (1.16)	2.7 (0.97)	2.3 (1.22)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C5D1 CFB					
n	25	37	34	67	
LS Mean (StdErr) [2]	-0.39 (0.250)	-0.64 (0.215)	-0.16 (0.207)	-0.48 (0.157)	
95% CI [2]	-0.89, 0.11	-1.07, -0.21	-0.57, 0.25	-0.79, -0.17	
Difference (95% CI) in CFB [2]		-0.25 (-0.81, 0.31)		-0.32 (-0.77, 0.13)	
p-value [3]		0.373		0.160	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	24	44	34	67	
Mean (StdDev)	2.2 (1.43)	2.1 (1.23)	2.7 (1.01)	2.1 (1.20)	
Median	2.5	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C6D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-0.54 (0.289)	-0.89 (0.240)	-0.12 (0.210)	-0.52 (0.158)	
95% CI [2]	-1.12, 0.03	-1.37, -0.41	-0.54, 0.30	-0.83, -0.21	
Difference (95% CI) in CFB [2]		-0.35 (-0.99, 0.29)		-0.40 (-0.86, 0.06)	
p-value [3]		0.281		0.086	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	24	44	34	67	
Mean (StdDev)	1.9 (1.36)	2.0 (1.21)	2.5 (0.99)	2.3 (1.15)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C7D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-0.50 (0.274)	-0.63 (0.219)	-0.25 (0.208)	-0.40 (0.157)	
95% CI [2]	-1.05, 0.04	-1.07, -0.20	-0.66, 0.16	-0.71, -0.09	
Difference (95% CI) in CFB [2]		-0.13 (-0.71, 0.45)		-0.15 (-0.60, 0.31)	
Hedges'G (95% CI) in CFB		-0.09 (-0.62, 0.42)		-0.12 (-0.54, 0.30)	
p-value [3]		0.652		0.518	
					0.954

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	30	49	35	70	
Mean (StdDev)	2.2 (1.24)	2.6 (1.01)	2.4 (1.03)	2.7 (1.12)	
Median	2.0	3.0	2.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	29	51	35	68	
Mean (StdDev)	2.0 (1.32)	2.0 (1.09)	2.1 (1.12)	2.1 (1.20)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	27	48	35	68	
LS Mean (StdErr) [2]	-0.15 (0.209)	-0.60 (0.173)	-0.19 (0.166)	-0.55 (0.129)	
95% CI [2]	-0.57, 0.27	-0.94, -0.25	-0.52, 0.14	-0.80, -0.29	
Difference (95% CI) in CFB [2]		-0.45 (-0.91, 0.02)		-0.36 (-0.73, -0.00)	
p-value [3]		0.060		0.050	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	29	44	34	66	
Mean (StdDev)	2.2 (1.24)	1.8 (1.21)	2.1 (1.15)	2.0 (1.16)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	27	43	34	66	
LS Mean (StdErr) [2]	-0.03 (0.194)	-0.81 (0.163)	-0.25 (0.173)	-0.65 (0.131)	
95% CI [2]	-0.42, 0.36	-1.13, -0.48	-0.59, 0.10	-0.91, -0.39	
Difference (95% CI) in CFB [2]		-0.78 (-1.20, -0.35)		-0.40 (-0.78, -0.02)	
p-value [3]		<0.001		0.039	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	22	44	34	69	
Mean (StdDev)	2.2 (1.27)	1.8 (1.16)	2.0 (1.10)	2.1 (1.19)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	20	43	34	68	
LS Mean (StdErr) [2]	0.09 (0.275)	-0.64 (0.221)	-0.32 (0.181)	-0.55 (0.136)	
95% CI [2]	-0.46, 0.65	-1.08, -0.20	-0.68, 0.04	-0.82, -0.28	
Difference (95% CI) in CFB [2]		-0.74 (-1.31, -0.17)		-0.23 (-0.62, 0.17)	
p-value [3]		0.012		0.255	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	26	40	34	68	
Mean (StdDev)	2.0 (1.30)	1.9 (1.03)	2.2 (1.15)	2.0 (1.25)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	25	37	34	67	
LS Mean (StdErr) [2]	-0.31 (0.265)	-0.74 (0.228)	-0.06 (0.182)	-0.64 (0.138)	
95% CI [2]	-0.84, 0.22	-1.19, -0.28	-0.42, 0.30	-0.92, -0.37	
Difference (95% CI) in CFB [2]		-0.42 (-1.02, 0.17)		-0.58 (-0.98, -0.18)	
p-value [3]		0.160		0.005	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	24	44	34	67	
Mean (StdDev)	2.0 (1.44)	1.6 (1.11)	2.0 (1.03)	2.0 (1.31)	
Median	1.5	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-0.32 (0.263)	-1.02 (0.218)	-0.25 (0.192)	-0.62 (0.145)	
95% CI [2]	-0.85, 0.21	-1.46, -0.58	-0.63, 0.13	-0.91, -0.34	
Difference (95% CI) in CFB [2]		-0.70 (-1.29, -0.12)		-0.37 (-0.79, 0.05)	
p-value [3]		0.020		0.081	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	24	44	34	67	
Mean (StdDev)	1.9 (1.42)	1.6 (1.17)	2.2 (0.98)	2.0 (1.30)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-0.23 (0.283)	-1.05 (0.226)	-0.11 (0.180)	-0.65 (0.136)	
95% CI [2]	-0.79, 0.34	-1.51, -0.60	-0.47, 0.25	-0.92, -0.38	
Difference (95% CI) in CFB [2]		-0.83 (-1.42, -0.23)		-0.54 (-0.94, -0.15)	
Hedges'G (95% CI) in CFB		-0.58 (-1.13, -0.07)		-0.50 (-0.93, -0.08)	
p-value [3]		0.007		0.007	
					0.389

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	30	49	35	70	
Mean (StdDev)	2.0 (1.35)	1.7 (1.46)	2.2 (1.35)	2.5 (1.36)	
Median	2.0	1.0	2.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	30	51	35	68	
Mean (StdDev)	1.5 (1.48)	1.2 (1.25)	1.8 (1.32)	2.0 (1.42)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	28	48	35	68	
LS Mean (StdErr) [2]	-0.48 (0.347)	-0.58 (0.289)	-0.36 (0.233)	-0.47 (0.180)	
95% CI [2]	-1.17, 0.21	-1.16, -0.01	-0.82, 0.10	-0.82, -0.11	
Difference (95% CI) in CFB [2]		-0.10 (-0.87, 0.67)		-0.11 (-0.61, 0.40)	
p-value [3]		0.795		0.681	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	29	43	34	66	
Mean (StdDev)	1.4 (1.27)	1.2 (1.25)	2.1 (1.30)	1.8 (1.43)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	27	43	34	66	
LS Mean (StdErr) [2]	-0.46 (0.355)	-0.28 (0.298)	-0.23 (0.248)	-0.78 (0.187)	
95% CI [2]	-1.16, 0.25	-0.88, 0.31	-0.72, 0.26	-1.15, -0.41	
Difference (95% CI) in CFB [2]		0.17 (-0.61, 0.96)		-0.55 (-1.09, -0.01)	
p-value [3]		0.662		0.046	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	22	44	34	69	
Mean (StdDev)	1.5 (1.30)	1.1 (1.13)	2.1 (1.12)	1.8 (1.37)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	20	43	34	68	
LS Mean (StdErr) [2]	-0.57 (0.453)	-0.60 (0.363)	-0.09 (0.242)	-0.68 (0.182)	
95% CI [2]	-1.48, 0.33	-1.32, 0.13	-0.57, 0.39	-1.04, -0.32	
Difference (95% CI) in CFB [2]		-0.02 (-0.96, 0.92)		-0.59 (-1.11, -0.06)	
p-value [3]		0.960		0.029	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	26	41	33	68	
Mean (StdDev)	1.5 (1.30)	1.0 (1.13)	2.2 (1.07)	1.7 (1.34)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	25	38	33	67	
LS Mean (StdErr) [2]	-0.44 (0.369)	-0.82 (0.312)	0.01 (0.259)	-0.76 (0.195)	
95% CI [2]	-1.18, 0.30	-1.44, -0.19	-0.50, 0.53	-1.15, -0.38	
Difference (95% CI) in CFB [2]		-0.38 (-1.20, 0.44)		-0.78 (-1.34, -0.21)	
p-value [3]		0.361		0.008	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	24	44	34	67	
Mean (StdDev)	1.8 (1.59)	0.9 (1.13)	2.1 (1.01)	1.9 (1.34)	
Median	1.5	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-0.38 (0.395)	-0.72 (0.327)	-0.08 (0.243)	-0.58 (0.183)	
95% CI [2]	-1.17, 0.41	-1.37, -0.06	-0.57, 0.40	-0.94, -0.21	
Difference (95% CI) in CFB [2]		-0.34 (-1.22, 0.54)		-0.49 (-1.02, 0.04)	
p-value [3]		0.443		0.068	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	24	44	34	67	
Mean (StdDev)	1.3 (1.27)	1.0 (1.16)	2.0 (1.27)	1.7 (1.34)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-0.63 (0.387)	-0.78 (0.310)	-0.03 (0.251)	-0.57 (0.189)	
95% CI [2]	-1.40, 0.15	-1.40, -0.16	-0.53, 0.47	-0.95, -0.20	
Difference (95% CI) in CFB [2]		-0.15 (-0.97, 0.66)		-0.54 (-1.09, 0.00)	
Hedges'G (95% CI) in CFB		-0.08 (-0.60, 0.44)		-0.36 (-0.79, 0.06)	
p-value [3]		0.710		0.051	
					0.444

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	30	49	35	70	
Mean (StdDev)	2.2 (1.30)	2.2 (1.32)	2.7 (1.20)	3.0 (1.20)	
Median	2.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	30	51	35	68	
Mean (StdDev)	2.0 (1.44)	1.8 (1.27)	2.6 (0.98)	2.3 (1.30)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	28	48	35	68	
LS Mean (StdErr) [2]	-0.33 (0.268)	-0.45 (0.223)	-0.05 (0.206)	-0.57 (0.159)	
95% CI [2]	-0.87, 0.20	-0.89, -0.00	-0.46, 0.36	-0.89, -0.25	
Difference (95% CI) in CFB [2]		-0.11 (-0.71, 0.48)		-0.52 (-0.97, -0.07)	
p-value [3]		0.705		0.023	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	29	43	34	66	
Mean (StdDev)	2.0 (1.21)	1.6 (1.33)	2.6 (1.16)	2.0 (1.25)	
Median	2.0	1.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	27	43	34	66	
LS Mean (StdErr) [2]	-0.23 (0.274)	-0.46 (0.231)	-0.15 (0.217)	-0.92 (0.163)	
95% CI [2]	-0.77, 0.32	-0.93, -0.00	-0.58, 0.28	-1.24, -0.59	
Difference (95% CI) in CFB [2]		-0.24 (-0.84, 0.37)		-0.77 (-1.25, -0.30)	
p-value [3]		0.436		0.002	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	22	44	34	69	
Mean (StdDev)	1.7 (1.45)	1.4 (1.20)	2.4 (1.16)	2.4 (1.28)	
Median	1.5	1.0	2.5	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	20	43	34	68	
LS Mean (StdErr) [2]	-0.55 (0.315)	-1.02 (0.253)	-0.16 (0.239)	-0.48 (0.180)	
95% CI [2]	-1.18, 0.08	-1.53, -0.52	-0.63, 0.31	-0.84, -0.12	
Difference (95% CI) in CFB [2]		-0.47 (-1.13, 0.18)		-0.32 (-0.84, 0.20)	
p-value [3]		0.155		0.225	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	26	41	33	68	
Mean (StdDev)	1.9 (1.37)	1.5 (1.19)	2.4 (1.06)	1.9 (1.27)	
Median	2.0	1.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	25	38	33	67	
LS Mean (StdErr) [2]	-0.48 (0.249)	-0.82 (0.211)	-0.05 (0.258)	-0.87 (0.194)	
95% CI [2]	-0.98, 0.01	-1.24, -0.40	-0.57, 0.46	-1.25, -0.48	
Difference (95% CI) in CFB [2]		-0.34 (-0.89, 0.22)		-0.81 (-1.38, -0.25)	
p-value [3]		0.232		0.005	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	24	44	34	67	
Mean (StdDev)	2.1 (1.47)	1.1 (1.07)	2.6 (1.04)	2.2 (1.29)	
Median	2.0	1.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-0.29 (0.273)	-1.08 (0.226)	0.09 (0.248)	-0.62 (0.187)	
95% CI [2]	-0.84, 0.25	-1.53, -0.63	-0.40, 0.58	-0.99, -0.25	
Difference (95% CI) in CFB [2]		-0.79 (-1.39, -0.18)		-0.71 (-1.25, -0.17)	
p-value [3]		0.012		0.010	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	24	44	34	67	
Mean (StdDev)	2.0 (1.41)	1.3 (1.29)	2.3 (1.17)	2.1 (1.35)	
Median	2.0	1.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-0.32 (0.294)	-0.99 (0.235)	-0.23 (0.269)	-0.74 (0.203)	
95% CI [2]	-0.91, 0.26	-1.46, -0.51	-0.76, 0.31	-1.14, -0.34	
Difference (95% CI) in CFB [2]		-0.66 (-1.28, -0.04)		-0.51 (-1.10, 0.08)	
Hedges'G (95% CI) in CFB		-0.44 (-0.99, 0.07)		-0.31 (-0.74, 0.10)	
p-value [3]		0.037		0.087	
					0.703

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	30	49	35	70	
Mean (StdDev)	2.0 (1.36)	2.4 (1.12)	2.6 (1.33)	2.5 (1.09)	
Median	2.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	30	51	35	68	
Mean (StdDev)	1.8 (1.10)	1.8 (1.18)	2.3 (1.23)	1.9 (1.23)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	28	48	35	68	
LS Mean (StdErr) [2]	-0.08 (0.265)	-0.51 (0.221)	-0.16 (0.207)	-0.50 (0.160)	
95% CI [2]	-0.61, 0.45	-0.95, -0.07	-0.57, 0.25	-0.82, -0.18	
Difference (95% CI) in CFB [2]		-0.43 (-1.01, 0.16)		-0.34 (-0.79, 0.11)	
p-value [3]		0.148		0.139	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	29	43	34	66	
Mean (StdDev)	1.6 (1.18)	1.7 (1.01)	2.3 (1.48)	1.8 (1.18)	
Median	1.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	27	43	34	66	
LS Mean (StdErr) [2]	-0.25 (0.236)	-0.47 (0.199)	-0.20 (0.208)	-0.60 (0.157)	
95% CI [2]	-0.72, 0.23	-0.87, -0.07	-0.61, 0.21	-0.91, -0.29	
Difference (95% CI) in CFB [2]		-0.23 (-0.75, 0.30)		-0.40 (-0.85, 0.05)	
p-value [3]		0.391		0.084	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	22	44	34	69	
Mean (StdDev)	1.8 (1.33)	1.5 (1.00)	2.2 (1.34)	1.9 (1.33)	
Median	1.5	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	20	43	34	68	
LS Mean (StdErr) [2]	-0.37 (0.336)	-0.94 (0.269)	-0.26 (0.235)	-0.55 (0.177)	
95% CI [2]	-1.04, 0.31	-1.48, -0.40	-0.73, 0.21	-0.90, -0.20	
Difference (95% CI) in CFB [2]		-0.57 (-1.27, 0.13)		-0.29 (-0.80, 0.22)	
p-value [3]		0.107		0.264	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	26	41	33	68	
Mean (StdDev)	1.6 (1.39)	1.6 (1.07)	2.4 (1.17)	1.7 (1.33)	
Median	2.0	1.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	25	38	33	67	
LS Mean (StdErr) [2]	-0.25 (0.289)	-0.78 (0.245)	-0.09 (0.248)	-0.81 (0.187)	
95% CI [2]	-0.83, 0.33	-1.27, -0.29	-0.58, 0.41	-1.18, -0.43	
Difference (95% CI) in CFB [2]		-0.53 (-1.17, 0.11)		-0.72 (-1.26, -0.18)	
p-value [3]		0.105		0.010	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	24	44	34	67	
Mean (StdDev)	1.9 (1.38)	1.4 (0.95)	2.4 (1.26)	1.7 (1.39)	
Median	2.0	1.5	2.5	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	0.18 (0.320)	-0.88 (0.265)	0.04 (0.232)	-0.68 (0.175)	
95% CI [2]	-0.46, 0.82	-1.41, -0.35	-0.42, 0.50	-1.03, -0.34	
Difference (95% CI) in CFB [2]		-1.05 (-1.76, -0.34)		-0.72 (-1.22, -0.21)	
p-value [3]		0.004		0.006	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	24	44	34	67	
Mean (StdDev)	1.5 (1.35)	1.5 (1.17)	2.3 (1.22)	1.8 (1.35)	
Median	1.0	1.0	2.5	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-0.05 (0.334)	-0.87 (0.267)	-0.09 (0.228)	-0.59 (0.172)	
95% CI [2]	-0.72, 0.61	-1.41, -0.34	-0.55, 0.36	-0.93, -0.25	
Difference (95% CI) in CFB [2]		-0.82 (-1.52, -0.11)		-0.49 (-0.99, 0.00)	
Hedges'G (95% CI) in CFB		-0.48 (-1.03, 0.03)		-0.36 (-0.79, 0.06)	
p-value [3]		0.024		0.051	
					0.435

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	30	49	35	70	
Mean (StdDev)	1.4 (1.54)	1.4 (1.53)	2.0 (1.48)	2.2 (1.41)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	30	51	35	68	
Mean (StdDev)	1.7 (1.62)	1.2 (1.33)	1.8 (1.44)	1.9 (1.50)	
Median	1.5	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	28	48	35	68	
LS Mean (StdErr) [2]	0.31 (0.252)	-0.22 (0.209)	-0.31 (0.197)	-0.40 (0.152)	
95% CI [2]	-0.19, 0.82	-0.63, 0.20	-0.70, 0.09	-0.70, -0.10	
Difference (95% CI) in CFB [2]		-0.53 (-1.08, 0.03)		-0.10 (-0.52, 0.33)	
p-value [3]		0.062		0.660	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	29	43	34	66	
Mean (StdDev)	1.6 (1.70)	1.0 (1.40)	1.5 (1.44)	1.6 (1.39)	
Median	1.0	0.0	1.0	1.5	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	27	43	34	66	
LS Mean (StdErr) [2]	0.12 (0.253)	-0.18 (0.213)	-0.47 (0.208)	-0.60 (0.156)	
95% CI [2]	-0.39, 0.62	-0.61, 0.24	-0.88, -0.06	-0.91, -0.29	
Difference (95% CI) in CFB [2]		-0.30 (-0.86, 0.26)		-0.13 (-0.58, 0.32)	
p-value [3]		0.291		0.565	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	22	44	34	69	
Mean (StdDev)	1.7 (1.52)	0.8 (1.20)	1.6 (1.24)	1.7 (1.41)	
Median	1.0	0.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	20	43	34	68	
LS Mean (StdErr) [2]	0.14 (0.381)	-0.33 (0.306)	-0.37 (0.230)	-0.42 (0.173)	
95% CI [2]	-0.63, 0.90	-0.94, 0.28	-0.83, 0.08	-0.76, -0.08	
Difference (95% CI) in CFB [2]		-0.47 (-1.26, 0.32)		-0.05 (-0.54, 0.45)	
p-value [3]		0.241		0.856	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	26	41	33	67	
Mean (StdDev)	1.2 (1.50)	1.0 (1.25)	1.5 (1.35)	1.5 (1.41)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	25	38	33	66	
LS Mean (StdErr) [2]	0.00 (0.342)	-0.22 (0.290)	-0.35 (0.242)	-0.64 (0.182)	
95% CI [2]	-0.68, 0.69	-0.80, 0.36	-0.83, 0.13	-1.01, -0.28	
Difference (95% CI) in CFB [2]		-0.23 (-0.99, 0.54)		-0.29 (-0.82, 0.24)	
p-value [3]		0.556		0.275	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	24	44	34	67	
Mean (StdDev)	1.3 (1.60)	0.8 (1.20)	1.5 (1.24)	1.7 (1.51)	
Median	0.5	0.0	1.5	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-0.10 (0.359)	-0.55 (0.298)	-0.43 (0.268)	-0.51 (0.202)	
95% CI [2]	-0.82, 0.62	-1.15, 0.04	-0.97, 0.10	-0.91, -0.10	
Difference (95% CI) in CFB [2]		-0.45 (-1.25, 0.35)		-0.07 (-0.65, 0.51)	
p-value [3]		0.262		0.810	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	24	44	34	67	
Mean (StdDev)	1.0 (1.23)	0.9 (1.39)	1.9 (1.44)	1.7 (1.39)	
Median	1.0	0.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-0.07 (0.327)	-0.24 (0.262)	-0.03 (0.269)	-0.48 (0.203)	
95% CI [2]	-0.72, 0.58	-0.77, 0.28	-0.56, 0.50	-0.88, -0.08	
Difference (95% CI) in CFB [2]		-0.17 (-0.86, 0.52)		-0.45 (-1.04, 0.14)	
Hedges'G (95% CI) in CFB		-0.10 (-0.63, 0.41)		-0.28 (-0.70, 0.14)	
p-value [3]		0.620		0.131	
					0.515

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	30	49	35	70	
Mean (StdDev)	1.7 (1.34)	2.0 (1.24)	2.5 (1.17)	2.7 (1.05)	
Median	2.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	30	51	35	68	
Mean (StdDev)	1.2 (1.19)	1.5 (1.12)	2.3 (1.09)	2.2 (1.12)	
Median	1.0	1.0	3.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C2D1 CFB					
n	28	48	35	68	
LS Mean (StdErr) [2]	-0.40 (0.221)	-0.44 (0.184)	-0.26 (0.159)	-0.46 (0.123)	
95% CI [2]	-0.84, 0.04	-0.80, -0.07	-0.57, 0.06	-0.70, -0.21	
Difference (95% CI) in CFB [2]		-0.03 (-0.52, 0.46)		-0.20 (-0.55, 0.15)	
p-value [3]		0.894		0.256	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	29	43	34	66	
Mean (StdDev)	1.6 (1.35)	1.3 (1.16)	2.2 (1.19)	1.9 (1.31)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	27	43	34	66	
LS Mean (StdErr) [2]	0.09 (0.213)	-0.49 (0.180)	-0.43 (0.199)	-0.85 (0.150)	
95% CI [2]	-0.34, 0.51	-0.85, -0.14	-0.83, -0.04	-1.15, -0.55	
Difference (95% CI) in CFB [2]		-0.58 (-1.05, -0.11)		-0.42 (-0.86, 0.01)	
p-value [3]		0.017		0.057	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	22	44	34	69	
Mean (StdDev)	1.5 (1.26)	1.1 (1.06)	2.1 (1.04)	1.9 (1.15)	
Median	1.5	1.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C4D1 CFB					
n	20	43	34	68	
LS Mean (StdErr) [2]	-0.10 (0.284)	-0.78 (0.227)	-0.39 (0.176)	-0.70 (0.133)	
95% CI [2]	-0.67, 0.46	-1.24, -0.33	-0.74, -0.04	-0.96, -0.44	
Difference (95% CI) in CFB [2]		-0.68 (-1.27, -0.09)		-0.31 (-0.70, 0.07)	
p-value [3]		0.024		0.108	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	26	41	33	68	
Mean (StdDev)	1.3 (1.37)	1.2 (1.18)	2.2 (0.89)	1.8 (1.22)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C5D1 CFB					
n	25	38	33	67	
LS Mean (StdErr) [2]	-0.50 (0.263)	-0.91 (0.223)	-0.29 (0.204)	-0.90 (0.154)	
95% CI [2]	-1.03, 0.02	-1.35, -0.46	-0.69, 0.12	-1.20, -0.59	
Difference (95% CI) in CFB [2]		-0.41 (-0.99, 0.18)		-0.61 (-1.05, -0.16)	
p-value [3]		0.171		0.008	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	24	44	34	67	
Mean (StdDev)	1.8 (1.46)	0.9 (1.10)	2.2 (0.99)	2.0 (1.33)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	0.16 (0.270)	-1.10 (0.224)	-0.21 (0.210)	-0.63 (0.158)	
95% CI [2]	-0.38, 0.70	-1.54, -0.65	-0.63, 0.21	-0.95, -0.32	
Difference (95% CI) in CFB [2]		-1.26 (-1.86, -0.66)		-0.42 (-0.88, 0.03)	
p-value [3]		<0.0001		0.069	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	24	44	34	67	
Mean (StdDev)	1.3 (1.42)	1.0 (1.20)	2.4 (1.15)	1.8 (1.34)	
Median	1.0	1.0	2.5	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-0.29 (0.259)	-0.85 (0.207)	-0.05 (0.212)	-0.74 (0.159)	
95% CI [2]	-0.81, 0.22	-1.26, -0.43	-0.47, 0.37	-1.05, -0.42	
Difference (95% CI) in CFB [2]		-0.56 (-1.10, -0.01)		-0.68 (-1.14, -0.22)	
Hedges'G (95% CI) in CFB		-0.42 (-0.96, 0.09)		-0.53 (-0.97, -0.12)	
p-value [3]		0.046		0.004	
					0.721

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	30	49	35	70	
Mean (StdDev)	1.5 (1.48)	1.8 (1.27)	2.4 (1.19)	2.4 (1.27)	
Median	1.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	30	51	35	68	
Mean (StdDev)	1.1 (1.20)	1.3 (1.18)	1.8 (1.13)	1.9 (1.29)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C2D1 CFB					
n	28	48	35	68	
LS Mean (StdErr) [2]	-0.41 (0.228)	-0.65 (0.190)	-0.42 (0.189)	-0.35 (0.146)	
95% CI [2]	-0.86, 0.05	-1.03, -0.27	-0.79, -0.04	-0.64, -0.06	
Difference (95% CI) in CFB [2]		-0.24 (-0.74, 0.27)		0.06 (-0.35, 0.47)	
p-value [3]		0.349		0.762	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	29	43	34	66	
Mean (StdDev)	1.2 (1.24)	1.3 (1.26)	1.9 (1.25)	1.6 (1.30)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	27	43	34	66	
LS Mean (StdErr) [2]	-0.31 (0.216)	-0.55 (0.182)	-0.31 (0.211)	-0.69 (0.159)	
95% CI [2]	-0.74, 0.13	-0.92, -0.19	-0.73, 0.11	-1.01, -0.38	
Difference (95% CI) in CFB [2]		-0.25 (-0.73, 0.23)		-0.38 (-0.84, 0.07)	
p-value [3]		0.306		0.100	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	22	44	34	69	
Mean (StdDev)	1.2 (1.14)	1.0 (1.05)	1.9 (1.10)	1.6 (1.33)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C4D1 CFB					
n	20	43	34	68	
LS Mean (StdErr) [2]	-0.64 (0.264)	-0.96 (0.211)	-0.37 (0.200)	-0.69 (0.151)	
95% CI [2]	-1.17, -0.12	-1.38, -0.54	-0.76, 0.03	-0.99, -0.39	
Difference (95% CI) in CFB [2]		-0.32 (-0.86, 0.23)		-0.32 (-0.75, 0.12)	
p-value [3]		0.251		0.148	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	26	41	33	68	
Mean (StdDev)	1.1 (1.34)	1.2 (1.12)	1.9 (1.19)	1.6 (1.27)	
Median	0.5	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	25	38	33	67	
LS Mean (StdErr) [2]	-0.41 (0.241)	-0.86 (0.205)	-0.31 (0.223)	-0.71 (0.168)	
95% CI [2]	-0.89, 0.08	-1.27, -0.45	-0.75, 0.13	-1.05, -0.38	
Difference (95% CI) in CFB [2]		-0.45 (-0.99, 0.08)		-0.40 (-0.89, 0.08)	
p-value [3]		0.096		0.104	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	24	44	34	67	
Mean (StdDev)	1.3 (1.37)	0.9 (1.20)	2.0 (1.11)	1.7 (1.35)	
Median	1.0	0.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-0.24 (0.254)	-1.08 (0.210)	-0.28 (0.220)	-0.64 (0.166)	
95% CI [2]	-0.74, 0.27	-1.50, -0.66	-0.72, 0.15	-0.97, -0.31	
Difference (95% CI) in CFB [2]		-0.84 (-1.40, -0.28)		-0.35 (-0.83, 0.13)	
p-value [3]		0.004		0.148	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	24	44	34	67	
Mean (StdDev)	1.1 (1.28)	0.8 (1.23)	1.9 (1.27)	1.6 (1.36)	
Median	1.0	0.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-0.09 (0.265)	-0.91 (0.212)	-0.26 (0.222)	-0.58 (0.168)	
95% CI [2]	-0.62, 0.44	-1.34, -0.49	-0.70, 0.18	-0.91, -0.25	
Difference (95% CI) in CFB [2]		-0.83 (-1.39, -0.27)		-0.32 (-0.81, 0.16)	
Hedges'G (95% CI) in CFB		-0.62 (-1.17, -0.11)		-0.24 (-0.67, 0.17)	
p-value [3]		0.004		0.188	
					0.160

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	30	49	35	70	
Mean (StdDev)	2.9 (0.83)	3.0 (0.90)	3.1 (1.00)	2.9 (1.08)	
Median	3.0	3.0	3.0	3.0	
Min, Max	1, 4	1, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	30	51	35	68	
Mean (StdDev)	2.5 (0.94)	2.6 (0.94)	2.6 (1.20)	2.4 (1.07)	
Median	2.5	3.0	3.0	2.0	
Min, Max	1, 4	1, 4	0, 4	0, 4	
C2D1 CFB					
n	28	48	35	68	
LS Mean (StdErr) [2]	-0.57 (0.184)	-0.48 (0.153)	-0.48 (0.184)	-0.46 (0.142)	
95% CI [2]	-0.94, -0.21	-0.78, -0.17	-0.84, -0.11	-0.75, -0.18	
Difference (95% CI) in CFB [2]		0.10 (-0.31, 0.50)		0.01 (-0.39, 0.41)	
p-value [3]		0.636		0.948	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	29	43	34	66	
Mean (StdDev)	2.6 (1.02)	2.4 (1.01)	2.6 (1.10)	2.1 (1.19)	
Median	3.0	2.0	3.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	27	43	34	66	
LS Mean (StdErr) [2]	-0.47 (0.189)	-0.52 (0.159)	-0.26 (0.200)	-0.66 (0.150)	
95% CI [2]	-0.84, -0.09	-0.84, -0.20	-0.66, 0.13	-0.96, -0.36	
Difference (95% CI) in CFB [2]		-0.05 (-0.47, 0.37)		-0.39 (-0.83, 0.04)	
p-value [3]		0.800		0.075	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	22	44	34	69	
Mean (StdDev)	2.4 (1.30)	2.3 (0.90)	2.4 (1.18)	2.3 (1.37)	
Median	3.0	2.0	2.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	20	43	34	68	
LS Mean (StdErr) [2]	-0.72 (0.248)	-0.75 (0.199)	-0.54 (0.206)	-0.41 (0.155)	
95% CI [2]	-1.21, -0.22	-1.15, -0.35	-0.95, -0.13	-0.72, -0.10	
Difference (95% CI) in CFB [2]		-0.03 (-0.55, 0.48)		0.13 (-0.31, 0.58)	
p-value [3]		0.896		0.554	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	26	41	34	68	
Mean (StdDev)	2.5 (1.14)	2.3 (0.99)	2.6 (0.95)	1.9 (1.41)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C5D1 CFB					
n	25	38	34	67	
LS Mean (StdErr) [2]	-0.54 (0.247)	-0.81 (0.209)	-0.39 (0.224)	-0.97 (0.170)	
95% CI [2]	-1.04, -0.05	-1.23, -0.39	-0.84, 0.06	-1.31, -0.63	
Difference (95% CI) in CFB [2]		-0.27 (-0.82, 0.28)		-0.58 (-1.07, -0.09)	
p-value [3]		0.330		0.020	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	24	44	34	67	
Mean (StdDev)	2.3 (1.27)	2.1 (1.03)	2.8 (1.13)	2.2 (1.36)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-0.49 (0.274)	-0.79 (0.227)	-0.10 (0.224)	-0.52 (0.169)	
95% CI [2]	-1.04, 0.06	-1.24, -0.33	-0.54, 0.35	-0.86, -0.19	
Difference (95% CI) in CFB [2]		-0.29 (-0.90, 0.32)		-0.43 (-0.92, 0.06)	
p-value [3]		0.340		0.085	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	24	44	34	67	
Mean (StdDev)	2.3 (1.19)	2.2 (0.94)	2.7 (1.03)	2.1 (1.35)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-0.59 (0.230)	-0.86 (0.184)	-0.20 (0.220)	-0.58 (0.165)	
95% CI [2]	-1.05, -0.13	-1.23, -0.49	-0.63, 0.24	-0.91, -0.25	
Difference (95% CI) in CFB [2]		-0.28 (-0.76, 0.21)		-0.38 (-0.86, 0.10)	
Hedges'G (95% CI) in CFB		-0.24 (-0.77, 0.28)		-0.28 (-0.71, 0.13)	
p-value [3]		0.256		0.120	
					0.839

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	30	49	35	70	
Mean (StdDev)	2.0 (1.51)	2.4 (1.20)	2.8 (1.32)	2.5 (1.25)	
Median	2.0	2.0	3.0	2.5	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	30	51	35	68	
Mean (StdDev)	1.9 (1.31)	2.0 (1.22)	2.4 (1.12)	1.9 (1.46)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	28	48	35	68	
LS Mean (StdErr) [2]	-0.07 (0.244)	-0.45 (0.203)	-0.43 (0.192)	-0.52 (0.149)	
95% CI [2]	-0.55, 0.42	-0.85, -0.04	-0.81, -0.05	-0.82, -0.23	
Difference (95% CI) in CFB [2]		-0.38 (-0.92, 0.16)		-0.09 (-0.51, 0.33)	
p-value [3]		0.164		0.670	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	29	43	34	66	
Mean (StdDev)	2.0 (1.39)	1.9 (1.21)	2.5 (0.99)	1.7 (1.34)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	27	43	34	66	
LS Mean (StdErr) [2]	-0.07 (0.277)	-0.60 (0.233)	-0.33 (0.205)	-0.75 (0.154)	
95% CI [2]	-0.63, 0.48	-1.07, -0.13	-0.74, 0.07	-1.05, -0.44	
Difference (95% CI) in CFB [2]		-0.53 (-1.14, 0.09)		-0.41 (-0.86, 0.03)	
p-value [3]		0.091		0.069	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	22	44	34	69	
Mean (StdDev)	1.8 (1.45)	1.8 (1.36)	2.2 (1.18)	1.9 (1.45)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	20	43	34	68	
LS Mean (StdErr) [2]	-0.19 (0.246)	-0.73 (0.197)	-0.55 (0.222)	-0.61 (0.167)	
95% CI [2]	-0.69, 0.30	-1.13, -0.34	-0.99, -0.11	-0.94, -0.28	
Difference (95% CI) in CFB [2]		-0.54 (-1.05, -0.03)		-0.06 (-0.55, 0.42)	
p-value [3]		0.038		0.793	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	26	41	34	68	
Mean (StdDev)	1.7 (1.52)	1.9 (1.23)	2.2 (1.39)	1.7 (1.58)	
Median	2.0	2.0	2.5	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	25	38	34	67	
LS Mean (StdErr) [2]	-0.28 (0.227)	-0.72 (0.192)	-0.51 (0.233)	-0.74 (0.177)	
95% CI [2]	-0.73, 0.17	-1.11, -0.34	-0.98, -0.05	-1.09, -0.39	
Difference (95% CI) in CFB [2]		-0.45 (-0.95, 0.06)		-0.23 (-0.73, 0.28)	
p-value [3]		0.082		0.376	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	24	44	34	67	
Mean (StdDev)	1.9 (1.45)	1.5 (1.30)	2.5 (1.13)	1.7 (1.44)	
Median	2.0	1.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	0.07 (0.282)	-0.89 (0.233)	-0.30 (0.214)	-0.77 (0.161)	
95% CI [2]	-0.50, 0.63	-1.36, -0.42	-0.73, 0.12	-1.09, -0.45	
Difference (95% CI) in CFB [2]		-0.96 (-1.58, -0.33)		-0.47 (-0.93, -0.00)	
p-value [3]		0.003		0.049	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	24	44	34	67	
Mean (StdDev)	1.7 (1.55)	1.3 (1.28)	2.3 (1.30)	1.7 (1.48)	
Median	1.5	1.0	3.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-0.32 (0.281)	-1.03 (0.225)	-0.37 (0.233)	-0.69 (0.176)	
95% CI [2]	-0.88, 0.25	-1.48, -0.58	-0.84, 0.09	-1.04, -0.34	
Difference (95% CI) in CFB [2]		-0.71 (-1.30, -0.12)		-0.31 (-0.82, 0.19)	
Hedges'G (95% CI) in CFB		-0.50 (-1.05, 0.01)		-0.22 (-0.65, 0.19)	
p-value [3]		0.019		0.222	
					0.290

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	30	49	35	70	
Mean (StdDev)	2.5 (1.25)	2.6 (1.01)	3.1 (0.97)	3.3 (0.85)	
Median	3.0	3.0	3.0	3.0	
Min, Max	0, 4	0, 4	0, 4	1, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	30	51	35	68	
Mean (StdDev)	1.9 (1.17)	1.9 (1.22)	2.5 (1.01)	2.6 (1.16)	
Median	2.0	2.0	2.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	28	48	35	68	
LS Mean (StdErr) [2]	-0.60 (0.223)	-0.74 (0.186)	-0.59 (0.184)	-0.73 (0.142)	
95% CI [2]	-1.05, -0.16	-1.11, -0.37	-0.95, -0.22	-1.01, -0.45	
Difference (95% CI) in CFB [2]		-0.14 (-0.63, 0.35)		-0.15 (-0.55, 0.25)	
p-value [3]		0.576		0.469	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	29	43	34	66	
Mean (StdDev)	2.0 (1.36)	1.8 (1.20)	2.7 (0.97)	2.2 (1.21)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C3D1 CFB					
n	27	43	34	66	
LS Mean (StdErr) [2]	-0.47 (0.238)	-0.73 (0.201)	-0.33 (0.209)	-1.05 (0.158)	
95% CI [2]	-0.94, 0.01	-1.13, -0.33	-0.75, 0.08	-1.37, -0.74	
Difference (95% CI) in CFB [2]		-0.26 (-0.79, 0.27)		-0.72 (-1.18, -0.27)	
p-value [3]		0.326		0.002	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	22	44	34	69	
Mean (StdDev)	2.1 (1.34)	1.7 (1.07)	2.7 (1.00)	2.3 (1.29)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C4D1 CFB					
n	20	43	34	68	
LS Mean (StdErr) [2]	-0.49 (0.258)	-0.96 (0.207)	-0.30 (0.212)	-0.95 (0.160)	
95% CI [2]	-1.01, 0.02	-1.37, -0.55	-0.72, 0.12	-1.26, -0.63	
Difference (95% CI) in CFB [2]		-0.47 (-1.00, 0.07)		-0.65 (-1.11, -0.19)	
p-value [3]		0.087		0.006	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	26	41	34	67	
Mean (StdDev)	1.8 (1.26)	1.8 (1.19)	2.6 (1.01)	2.2 (1.20)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C5D1 CFB					
n	25	38	34	66	
LS Mean (StdErr) [2]	-0.67 (0.207)	-0.95 (0.175)	-0.31 (0.225)	-1.04 (0.171)	
95% CI [2]	-1.09, -0.26	-1.30, -0.60	-0.76, 0.13	-1.38, -0.70	
Difference (95% CI) in CFB [2]		-0.28 (-0.74, 0.18)		-0.73 (-1.22, -0.24)	
p-value [3]		0.233		0.004	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	24	44	34	67	
Mean (StdDev)	2.2 (1.24)	1.4 (1.10)	2.7 (1.07)	2.3 (1.33)	
Median	2.0	1.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-0.41 (0.226)	-1.35 (0.187)	-0.34 (0.231)	-1.00 (0.174)	
95% CI [2]	-0.86, 0.04	-1.72, -0.97	-0.80, 0.12	-1.35, -0.65	
Difference (95% CI) in CFB [2]		-0.94 (-1.44, -0.44)		-0.66 (-1.17, -0.16)	
p-value [3]		<0.001		0.010	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	24	44	34	67	
Mean (StdDev)	1.8 (1.42)	1.3 (1.18)	2.6 (1.16)	2.3 (1.30)	
Median	2.0	1.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-0.49 (0.267)	-1.13 (0.214)	-0.31 (0.219)	-0.86 (0.165)	
95% CI [2]	-1.03, 0.04	-1.55, -0.70	-0.75, 0.12	-1.19, -0.53	
Difference (95% CI) in CFB [2]		-0.63 (-1.19, -0.07)		-0.54 (-1.02, -0.07)	
Hedges'G (95% CI) in CFB		-0.47 (-1.01, 0.04)		-0.41 (-0.84, 0.00)	
p-value [3]		0.028		0.026	
					0.797

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	30	49	35	70	
Mean (StdDev)	2.9 (1.04)	3.1 (1.01)	3.3 (0.78)	3.1 (0.89)	
Median	3.0	3.0	3.0	3.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	30	51	35	68	
Mean (StdDev)	2.4 (1.07)	2.3 (1.02)	2.8 (0.91)	2.4 (1.12)	
Median	2.0	2.0	3.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	28	48	35	68	
LS Mean (StdErr) [2]	-0.44 (0.188)	-0.90 (0.156)	-0.44 (0.176)	-0.70 (0.136)	
95% CI [2]	-0.81, -0.06	-1.21, -0.59	-0.79, -0.09	-0.97, -0.43	
Difference (95% CI) in CFB [2]		-0.46 (-0.88, -0.05)		-0.25 (-0.64, 0.13)	
p-value [3]		0.030		0.195	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	29	43	34	66	
Mean (StdDev)	2.4 (1.21)	2.2 (1.15)	2.6 (0.99)	2.1 (1.19)	
Median	3.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	27	43	34	66	
LS Mean (StdErr) [2]	-0.45 (0.228)	-0.91 (0.192)	-0.63 (0.199)	-1.04 (0.150)	
95% CI [2]	-0.90, 0.01	-1.29, -0.52	-1.02, -0.23	-1.34, -0.75	
Difference (95% CI) in CFB [2]		-0.46 (-0.97, 0.04)		-0.42 (-0.85, 0.02)	
p-value [3]		0.072		0.060	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	22	44	34	69	
Mean (StdDev)	2.4 (1.36)	2.1 (1.03)	2.5 (0.99)	2.1 (1.21)	
Median	2.0	2.0	2.5	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C4D1 CFB					
n	20	43	34	68	
LS Mean (StdErr) [2]	-0.51 (0.267)	-1.15 (0.214)	-0.74 (0.187)	-1.07 (0.141)	
95% CI [2]	-1.04, 0.02	-1.57, -0.72	-1.11, -0.37	-1.34, -0.79	
Difference (95% CI) in CFB [2]		-0.63 (-1.19, -0.08)		-0.32 (-0.73, 0.08)	
p-value [3]		0.025		0.116	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	26	41	34	68	
Mean (StdDev)	2.2 (1.35)	2.2 (1.12)	2.6 (1.21)	2.1 (1.24)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	25	38	34	67	
LS Mean (StdErr) [2]	-0.47 (0.255)	-0.99 (0.216)	-0.58 (0.220)	-0.98 (0.167)	
95% CI [2]	-0.98, 0.04	-1.42, -0.55	-1.02, -0.14	-1.31, -0.65	
Difference (95% CI) in CFB [2]		-0.51 (-1.08, 0.06)		-0.40 (-0.88, 0.08)	
p-value [3]		0.077		0.101	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	24	44	34	67	
Mean (StdDev)	2.4 (1.17)	1.8 (1.14)	2.8 (1.13)	2.2 (1.34)	
Median	3.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-0.50 (0.266)	-1.40 (0.220)	-0.44 (0.223)	-0.96 (0.168)	
95% CI [2]	-1.03, 0.03	-1.84, -0.96	-0.88, 0.00	-1.29, -0.62	
Difference (95% CI) in CFB [2]		-0.90 (-1.49, -0.31)		-0.52 (-1.00, -0.03)	
p-value [3]		0.003		0.037	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	24	44	34	67	
Mean (StdDev)	2.1 (1.44)	1.8 (1.29)	2.6 (1.21)	2.1 (1.26)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-0.49 (0.305)	-1.24 (0.244)	-0.53 (0.213)	-0.97 (0.161)	
95% CI [2]	-1.10, 0.12	-1.72, -0.75	-0.95, -0.10	-1.28, -0.65	
Difference (95% CI) in CFB [2]		-0.75 (-1.39, -0.10)		-0.44 (-0.90, 0.03)	
Hedges'G (95% CI) in CFB		-0.48 (-1.03, 0.03)		-0.34 (-0.77, 0.08)	
p-value [3]		0.024		0.064	
					0.433

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	30	49	35	70	
Mean (StdDev)	2.5 (1.41)	2.0 (1.46)	2.1 (1.46)	1.8 (1.51)	
Median	3.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	30	51	35	68	
Mean (StdDev)	1.9 (1.47)	1.5 (1.46)	2.0 (1.40)	1.5 (1.40)	
Median	1.5	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	28	48	35	68	
LS Mean (StdErr) [2]	-0.35 (0.255)	-0.29 (0.213)	0.20 (0.213)	-0.06 (0.165)	
95% CI [2]	-0.86, 0.16	-0.71, 0.14	-0.22, 0.62	-0.39, 0.27	
Difference (95% CI) in CFB [2]		0.06 (-0.50, 0.63)		-0.26 (-0.72, 0.20)	
p-value [3]		0.830		0.267	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	29	43	34	66	
Mean (StdDev)	2.1 (1.48)	1.6 (1.48)	1.9 (1.31)	1.3 (1.38)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	27	43	34	66	
LS Mean (StdErr) [2]	-0.31 (0.265)	-0.37 (0.223)	0.09 (0.255)	-0.33 (0.192)	
95% CI [2]	-0.84, 0.22	-0.81, 0.08	-0.42, 0.60	-0.71, 0.05	
Difference (95% CI) in CFB [2]		-0.05 (-0.64, 0.53)		-0.42 (-0.98, 0.13)	
p-value [3]		0.855		0.134	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	22	44	34	69	
Mean (StdDev)	2.0 (1.35)	1.5 (1.42)	1.8 (1.25)	1.5 (1.44)	
Median	2.0	1.5	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	20	43	34	68	
LS Mean (StdErr) [2]	-0.50 (0.253)	-0.28 (0.203)	-0.10 (0.243)	-0.22 (0.183)	
95% CI [2]	-1.00, 0.01	-0.68, 0.13	-0.58, 0.38	-0.58, 0.15	
Difference (95% CI) in CFB [2]		0.22 (-0.31, 0.74)		-0.12 (-0.64, 0.41)	
p-value [3]		0.407		0.665	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	26	41	34	68	
Mean (StdDev)	1.6 (1.36)	1.5 (1.42)	2.0 (1.34)	1.4 (1.40)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	25	38	34	67	
LS Mean (StdErr) [2]	-0.78 (0.303)	-0.36 (0.256)	0.17 (0.246)	-0.31 (0.187)	
95% CI [2]	-1.39, -0.18	-0.87, 0.15	-0.32, 0.66	-0.68, 0.06	
Difference (95% CI) in CFB [2]		0.43 (-0.25, 1.10)		-0.48 (-1.01, 0.06)	
p-value [3]		0.212		0.079	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	24	44	34	67	
Mean (StdDev)	1.9 (1.56)	1.4 (1.34)	1.9 (1.40)	1.4 (1.39)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-0.77 (0.296)	-0.54 (0.245)	0.05 (0.266)	-0.34 (0.201)	
95% CI [2]	-1.36, -0.17	-1.03, -0.05	-0.48, 0.58	-0.74, 0.06	
Difference (95% CI) in CFB [2]		0.23 (-0.43, 0.89)		-0.39 (-0.97, 0.19)	
p-value [3]		0.491		0.189	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	24	44	34	67	
Mean (StdDev)	2.1 (1.56)	1.2 (1.29)	1.9 (1.46)	1.3 (1.40)	
Median	2.5	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-0.26 (0.270)	-0.46 (0.217)	0.18 (0.281)	-0.26 (0.212)	
95% CI [2]	-0.80, 0.28	-0.89, -0.03	-0.38, 0.74	-0.68, 0.16	
Difference (95% CI) in CFB [2]		-0.20 (-0.77, 0.37)		-0.43 (-1.05, 0.18)	
Hedges'G (95% CI) in CFB		-0.15 (-0.67, 0.37)		-0.25 (-0.68, 0.16)	
p-value [3]		0.485		0.163	
					0.609

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	30	49	35	70	
Mean (StdDev)	2.0 (1.43)	1.9 (1.25)	1.5 (1.01)	1.7 (1.37)	
Median	2.0	2.0	1.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	30	51	35	68	
Mean (StdDev)	1.7 (1.18)	1.4 (1.30)	1.3 (1.00)	1.3 (1.24)	
Median	2.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 3	0, 4	
C2D1 CFB					
n	28	48	35	68	
LS Mean (StdErr) [2]	-0.51 (0.196)	-0.55 (0.163)	-0.16 (0.154)	-0.38 (0.119)	
95% CI [2]	-0.90, -0.12	-0.87, -0.22	-0.46, 0.15	-0.61, -0.14	
Difference (95% CI) in CFB [2]		-0.03 (-0.46, 0.40)		-0.22 (-0.56, 0.11)	
p-value [3]		0.882		0.193	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	29	43	34	66	
Mean (StdDev)	1.7 (1.10)	1.3 (1.29)	1.4 (1.21)	1.0 (1.16)	
Median	2.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	27	43	34	66	
LS Mean (StdErr) [2]	-0.45 (0.248)	-0.64 (0.209)	-0.14 (0.209)	-0.72 (0.158)	
95% CI [2]	-0.95, 0.04	-1.06, -0.23	-0.55, 0.28	-1.03, -0.41	
Difference (95% CI) in CFB [2]		-0.19 (-0.74, 0.36)		-0.58 (-1.04, -0.13)	
p-value [3]		0.497		0.013	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	22	44	34	69	
Mean (StdDev)	1.6 (1.22)	1.1 (1.19)	1.6 (1.13)	1.1 (1.21)	
Median	2.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	20	43	34	68	
LS Mean (StdErr) [2]	-0.71 (0.282)	-0.78 (0.226)	-0.02 (0.212)	-0.72 (0.159)	
95% CI [2]	-1.27, -0.14	-1.23, -0.33	-0.44, 0.40	-1.04, -0.40	
Difference (95% CI) in CFB [2]		-0.07 (-0.66, 0.51)		-0.70 (-1.15, -0.24)	
p-value [3]		0.803		0.003	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	26	41	34	68	
Mean (StdDev)	1.5 (1.07)	1.1 (1.24)	1.5 (1.21)	1.0 (1.21)	
Median	2.0	1.0	1.0	0.5	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	25	38	34	67	
LS Mean (StdErr) [2]	-0.83 (0.221)	-0.93 (0.187)	-0.06 (0.211)	-0.75 (0.160)	
95% CI [2]	-1.28, -0.39	-1.30, -0.55	-0.47, 0.36	-1.07, -0.43	
Difference (95% CI) in CFB [2]		-0.09 (-0.58, 0.40)		-0.69 (-1.15, -0.24)	
p-value [3]		0.712		0.003	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	24	44	34	67	
Mean (StdDev)	1.5 (1.10)	1.0 (1.17)	1.6 (1.23)	1.2 (1.22)	
Median	2.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-0.87 (0.246)	-0.94 (0.204)	0.06 (0.193)	-0.60 (0.146)	
95% CI [2]	-1.36, -0.38	-1.34, -0.53	-0.33, 0.44	-0.89, -0.31	
Difference (95% CI) in CFB [2]		-0.07 (-0.61, 0.48)		-0.66 (-1.08, -0.23)	
p-value [3]		0.807		0.003	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	24	44	34	67	
Mean (StdDev)	1.1 (1.08)	1.0 (1.02)	1.5 (1.13)	1.0 (1.26)	
Median	1.0	1.0	1.0	0.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-1.18 (0.218)	-0.93 (0.174)	0.07 (0.201)	-0.56 (0.151)	
95% CI [2]	-1.62, -0.74	-1.28, -0.58	-0.32, 0.47	-0.86, -0.26	
Difference (95% CI) in CFB [2]		0.25 (-0.21, 0.70)		-0.63 (-1.07, -0.19)	
Hedges'G (95% CI) in CFB		0.22 (-0.29, 0.75)		-0.52 (-0.95, -0.10)	
p-value [3]		0.286		0.005	
					0.013

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	30	49	35	70	
Mean (StdDev)	1.1 (1.33)	1.5 (1.57)	1.4 (1.24)	1.4 (1.41)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	30	51	35	68	
Mean (StdDev)	1.3 (1.47)	1.3 (1.26)	1.1 (1.24)	1.2 (1.45)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	28	48	35	68	
LS Mean (StdErr) [2]	0.29 (0.193)	-0.09 (0.161)	-0.15 (0.203)	-0.11 (0.157)	
95% CI [2]	-0.10, 0.67	-0.41, 0.23	-0.55, 0.26	-0.42, 0.20	
Difference (95% CI) in CFB [2]		-0.38 (-0.81, 0.05)		0.04 (-0.41, 0.48)	
p-value [3]		0.079		0.865	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	29	43	34	66	
Mean (StdDev)	1.0 (1.07)	1.2 (1.34)	1.1 (1.31)	0.9 (1.17)	
Median	1.0	1.0	1.0	0.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	27	43	34	66	
LS Mean (StdErr) [2]	0.01 (0.260)	-0.16 (0.218)	-0.14 (0.210)	-0.42 (0.158)	
95% CI [2]	-0.51, 0.53	-0.60, 0.27	-0.56, 0.27	-0.74, -0.11	
Difference (95% CI) in CFB [2]		-0.18 (-0.75, 0.40)		-0.28 (-0.74, 0.18)	
p-value [3]		0.543		0.228	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	22	44	34	69	
Mean (StdDev)	1.3 (1.21)	1.1 (1.22)	1.4 (1.33)	1.0 (1.26)	
Median	1.0	1.0	1.0	0.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	20	43	34	68	
LS Mean (StdErr) [2]	-0.17 (0.316)	-0.54 (0.253)	0.07 (0.212)	-0.44 (0.159)	
95% CI [2]	-0.80, 0.47	-1.05, -0.04	-0.35, 0.49	-0.76, -0.13	
Difference (95% CI) in CFB [2]		-0.38 (-1.03, 0.28)		-0.51 (-0.97, -0.06)	
p-value [3]		0.254		0.029	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	26	41	34	68	
Mean (StdDev)	1.2 (1.29)	1.0 (1.29)	1.3 (1.24)	0.9 (1.20)	
Median	1.0	0.0	1.0	0.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	25	38	34	67	
LS Mean (StdErr) [2]	-0.14 (0.242)	-0.56 (0.205)	-0.00 (0.210)	-0.53 (0.159)	
95% CI [2]	-0.63, 0.34	-0.98, -0.15	-0.42, 0.41	-0.85, -0.21	
Difference (95% CI) in CFB [2]		-0.42 (-0.96, 0.12)		-0.53 (-0.98, -0.07)	
p-value [3]		0.122		0.024	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	24	44	34	67	
Mean (StdDev)	1.2 (1.27)	0.9 (1.21)	1.3 (1.24)	0.9 (1.20)	
Median	1.0	0.0	1.0	0.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-0.15 (0.282)	-0.65 (0.234)	0.01 (0.203)	-0.48 (0.153)	
95% CI [2]	-0.72, 0.41	-1.12, -0.18	-0.40, 0.41	-0.78, -0.17	
Difference (95% CI) in CFB [2]		-0.50 (-1.12, 0.13)		-0.48 (-0.93, -0.04)	
p-value [3]		0.119		0.033	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	24	44	34	67	
Mean (StdDev)	0.9 (1.10)	0.8 (1.11)	1.3 (1.25)	1.0 (1.34)	
Median	1.0	0.0	1.0	0.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C7D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-0.24 (0.277)	-0.58 (0.221)	0.12 (0.202)	-0.34 (0.152)	
95% CI [2]	-0.79, 0.32	-1.02, -0.14	-0.28, 0.52	-0.64, -0.04	
Difference (95% CI) in CFB [2]		-0.34 (-0.93, 0.24)		-0.46 (-0.90, -0.02)	
Hedges'G (95% CI) in CFB		-0.24 (-0.78, 0.27)		-0.37 (-0.80, 0.04)	
p-value [3]		0.243		0.042	
					0.804

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	30	49	35	70	
Mean (StdDev)	1.9 (1.20)	2.1 (1.17)	2.1 (1.05)	1.9 (1.37)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	30	51	35	68	
Mean (StdDev)	1.4 (1.30)	1.5 (1.27)	1.6 (1.22)	1.5 (1.26)	
Median	1.0	1.0	2.0	1.5	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	28	48	35	68	
LS Mean (StdErr) [2]	-0.50 (0.232)	-0.87 (0.193)	-0.51 (0.193)	-0.41 (0.149)	
95% CI [2]	-0.96, -0.03	-1.25, -0.48	-0.89, -0.13	-0.70, -0.11	
Difference (95% CI) in CFB [2]		-0.37 (-0.88, 0.14)		0.11 (-0.31, 0.53)	
p-value [3]		0.153		0.618	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	29	43	34	66	
Mean (StdDev)	1.7 (1.17)	1.5 (1.08)	1.5 (1.08)	1.3 (1.17)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C3D1 CFB					
n	27	43	34	66	
LS Mean (StdErr) [2]	-0.06 (0.257)	-0.51 (0.216)	-0.68 (0.167)	-0.69 (0.126)	
95% CI [2]	-0.57, 0.45	-0.95, -0.08	-1.01, -0.35	-0.94, -0.44	
Difference (95% CI) in CFB [2]		-0.45 (-1.02, 0.12)		-0.01 (-0.37, 0.35)	
p-value [3]		0.116		0.953	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	22	44	34	69	
Mean (StdDev)	1.4 (1.43)	1.2 (1.17)	1.7 (1.12)	1.5 (1.24)	
Median	1.0	1.0	1.5	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	20	43	34	68	
LS Mean (StdErr) [2]	-0.27 (0.306)	-1.05 (0.246)	-0.43 (0.204)	-0.46 (0.154)	
95% CI [2]	-0.89, 0.34	-1.54, -0.56	-0.84, -0.03	-0.77, -0.15	
Difference (95% CI) in CFB [2]		-0.78 (-1.41, -0.14)		-0.03 (-0.47, 0.42)	
p-value [3]		0.017		0.904	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	26	41	34	68	
Mean (StdDev)	1.2 (1.35)	1.0 (1.11)	1.7 (1.24)	1.2 (1.24)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	25	38	34	67	
LS Mean (StdErr) [2]	-0.50 (0.266)	-1.06 (0.225)	-0.31 (0.207)	-0.67 (0.157)	
95% CI [2]	-1.03, 0.03	-1.51, -0.61	-0.72, 0.10	-0.98, -0.36	
Difference (95% CI) in CFB [2]		-0.56 (-1.15, 0.04)		-0.35 (-0.80, 0.10)	
p-value [3]		0.066		0.122	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	24	44	34	67	
Mean (StdDev)	1.5 (1.35)	0.9 (1.09)	1.6 (1.26)	1.1 (1.14)	
Median	1.5	0.0	1.5	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-0.24 (0.278)	-1.58 (0.231)	-0.42 (0.209)	-0.79 (0.158)	
95% CI [2]	-0.80, 0.32	-2.04, -1.12	-0.84, -0.01	-1.10, -0.48	
Difference (95% CI) in CFB [2]		-1.34 (-1.96, -0.72)		-0.37 (-0.82, 0.09)	
p-value [3]		<0.0001		0.112	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	24	44	34	67	
Mean (StdDev)	1.5 (1.44)	1.1 (1.13)	1.6 (1.30)	1.2 (1.32)	
Median	1.5	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-0.15 (0.358)	-0.93 (0.286)	-0.35 (0.226)	-0.67 (0.170)	
95% CI [2]	-0.87, 0.57	-1.50, -0.36	-0.80, 0.09	-1.00, -0.33	
Difference (95% CI) in CFB [2]		-0.78 (-1.53, -0.03)		-0.31 (-0.80, 0.18)	
Hedges'G (95% CI) in CFB		-0.43 (-0.97, 0.08)		-0.23 (-0.65, 0.19)	
p-value [3]		0.042		0.211	
					0.269

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	30	49	35	70	
Mean (StdDev)	2.3 (1.12)	2.5 (1.17)	2.3 (0.91)	2.2 (1.21)	
Median	2.0	3.0	2.0	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	30	51	35	68	
Mean (StdDev)	1.9 (1.20)	1.6 (1.25)	1.6 (1.06)	1.8 (1.33)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	28	48	35	68	
LS Mean (StdErr) [2]	-0.25 (0.215)	-0.89 (0.179)	-0.66 (0.195)	-0.41 (0.151)	
95% CI [2]	-0.68, 0.18	-1.25, -0.54	-1.05, -0.27	-0.71, -0.11	
Difference (95% CI) in CFB [2]		-0.65 (-1.12, -0.17)		0.25 (-0.17, 0.68)	
p-value [3]		0.008		0.240	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	29	43	34	66	
Mean (StdDev)	1.8 (1.24)	1.6 (1.20)	1.9 (1.02)	1.3 (1.07)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	27	43	34	66	
LS Mean (StdErr) [2]	-0.43 (0.264)	-0.85 (0.222)	-0.45 (0.196)	-0.84 (0.148)	
95% CI [2]	-0.96, 0.09	-1.30, -0.41	-0.84, -0.06	-1.14, -0.55	
Difference (95% CI) in CFB [2]		-0.42 (-1.00, 0.16)		-0.40 (-0.82, 0.03)	
p-value [3]		0.155		0.069	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	22	44	34	68	
Mean (StdDev)	1.8 (1.18)	1.4 (1.17)	1.8 (1.11)	1.5 (1.32)	
Median	2.0	1.5	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	20	43	34	67	
LS Mean (StdErr) [2]	-0.59 (0.273)	-1.24 (0.219)	-0.60 (0.220)	-0.82 (0.166)	
95% CI [2]	-1.14, -0.05	-1.68, -0.80	-1.04, -0.16	-1.15, -0.49	
Difference (95% CI) in CFB [2]		-0.65 (-1.22, -0.08)		-0.22 (-0.70, 0.26)	
p-value [3]		0.025		0.360	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	26	41	34	68	
Mean (StdDev)	1.5 (1.48)	1.4 (1.16)	1.8 (1.20)	1.4 (1.28)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	25	38	34	67	
LS Mean (StdErr) [2]	-0.71 (0.292)	-1.10 (0.247)	-0.61 (0.223)	-0.96 (0.169)	
95% CI [2]	-1.30, -0.13	-1.59, -0.60	-1.05, -0.17	-1.29, -0.62	
Difference (95% CI) in CFB [2]		-0.38 (-1.03, 0.27)		-0.35 (-0.83, 0.14)	
p-value [3]		0.243		0.158	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	24	44	34	67	
Mean (StdDev)	1.9 (1.38)	1.1 (1.17)	1.6 (1.13)	1.5 (1.29)	
Median	2.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-0.37 (0.259)	-1.58 (0.215)	-0.73 (0.232)	-0.77 (0.175)	
95% CI [2]	-0.89, 0.15	-2.01, -1.15	-1.19, -0.27	-1.12, -0.43	
Difference (95% CI) in CFB [2]		-1.21 (-1.79, -0.64)		-0.04 (-0.55, 0.46)	
p-value [3]		<0.0001		0.866	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	24	44	34	67	
Mean (StdDev)	1.5 (1.25)	1.2 (1.16)	1.6 (1.23)	1.4 (1.32)	
Median	2.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-0.65 (0.304)	-1.14 (0.244)	-0.57 (0.228)	-0.70 (0.172)	
95% CI [2]	-1.26, -0.05	-1.63, -0.65	-1.02, -0.12	-1.04, -0.36	
Difference (95% CI) in CFB [2]		-0.48 (-1.12, 0.16)		-0.13 (-0.63, 0.37)	
Hedges'G (95% CI) in CFB		-0.31 (-0.85, 0.20)		-0.09 (-0.51, 0.32)	
p-value [3]		0.137		0.608	
					0.365

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	30	49	35	70	
Mean (StdDev)	2.5 (1.25)	2.7 (1.07)	2.7 (1.04)	2.7 (1.11)	
Median	3.0	3.0	3.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	30	51	35	68	
Mean (StdDev)	2.2 (1.07)	2.2 (1.23)	2.4 (1.19)	2.2 (1.17)	
Median	2.0	2.0	2.0	2.5	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	28	48	35	68	
LS Mean (StdErr) [2]	-0.21 (0.187)	-0.54 (0.155)	-0.39 (0.193)	-0.54 (0.149)	
95% CI [2]	-0.58, 0.16	-0.85, -0.23	-0.78, -0.01	-0.84, -0.25	
Difference (95% CI) in CFB [2]		-0.34 (-0.75, 0.08)		-0.15 (-0.57, 0.27)	
p-value [3]		0.109		0.479	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	29	44	34	66	
Mean (StdDev)	2.2 (1.18)	2.2 (1.16)	2.2 (1.18)	2.0 (1.14)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	27	43	34	66	
LS Mean (StdErr) [2]	-0.24 (0.202)	-0.34 (0.170)	-0.62 (0.200)	-0.82 (0.151)	
95% CI [2]	-0.64, 0.17	-0.68, -0.00	-1.02, -0.22	-1.12, -0.52	
Difference (95% CI) in CFB [2]		-0.11 (-0.55, 0.34)		-0.20 (-0.63, 0.24)	
p-value [3]		0.635		0.372	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	22	44	34	69	
Mean (StdDev)	2.2 (1.30)	2.0 (1.19)	2.5 (1.02)	2.1 (1.15)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C4D1 CFB					
n	20	43	34	68	
LS Mean (StdErr) [2]	-0.34 (0.316)	-0.63 (0.254)	-0.24 (0.201)	-0.71 (0.152)	
95% CI [2]	-0.98, 0.29	-1.14, -0.12	-0.64, 0.16	-1.01, -0.41	
Difference (95% CI) in CFB [2]		-0.29 (-0.94, 0.37)		-0.47 (-0.91, -0.03)	
p-value [3]		0.388		0.035	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	26	41	34	68	
Mean (StdDev)	2.0 (1.25)	2.0 (1.05)	2.4 (0.99)	2.1 (1.20)	
Median	2.0	2.0	2.5	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C5D1 CFB					
n	25	38	34	67	
LS Mean (StdErr) [2]	-0.41 (0.285)	-0.63 (0.241)	-0.33 (0.220)	-0.77 (0.167)	
95% CI [2]	-0.98, 0.16	-1.11, -0.15	-0.76, 0.11	-1.10, -0.44	
Difference (95% CI) in CFB [2]		-0.22 (-0.85, 0.42)		-0.45 (-0.93, 0.03)	
p-value [3]		0.492		0.067	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	24	44	34	67	
Mean (StdDev)	2.2 (1.28)	1.7 (0.99)	2.4 (1.21)	2.0 (1.24)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C6D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-0.31 (0.278)	-0.99 (0.231)	-0.27 (0.230)	-0.80 (0.174)	
95% CI [2]	-0.87, 0.24	-1.45, -0.53	-0.73, 0.19	-1.14, -0.45	
Difference (95% CI) in CFB [2]		-0.68 (-1.30, -0.06)		-0.53 (-1.03, -0.02)	
p-value [3]		0.032		0.040	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	24	44	34	67	
Mean (StdDev)	1.9 (1.35)	1.7 (1.15)	2.5 (1.11)	1.9 (1.17)	
Median	2.0	2.0	2.5	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-0.23 (0.274)	-0.81 (0.219)	-0.19 (0.222)	-0.75 (0.168)	
95% CI [2]	-0.78, 0.32	-1.25, -0.37	-0.63, 0.25	-1.08, -0.42	
Difference (95% CI) in CFB [2]		-0.58 (-1.16, -0.01)		-0.56 (-1.04, -0.07)	
Hedges'G (95% CI) in CFB		-0.42 (-0.96, 0.09)		-0.41 (-0.85, 0.00)	
p-value [3]		0.047		0.025	
					0.988

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	30	49	35	70	
Mean (StdDev)	2.2 (1.44)	2.3 (1.28)	2.3 (1.27)	1.9 (1.31)	
Median	2.0	3.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	30	51	35	68	
Mean (StdDev)	1.8 (1.37)	1.8 (1.39)	2.0 (1.22)	1.6 (1.26)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	28	48	35	68	
LS Mean (StdErr) [2]	-0.27 (0.218)	-0.53 (0.181)	-0.20 (0.180)	-0.18 (0.139)	
95% CI [2]	-0.71, 0.16	-0.89, -0.17	-0.56, 0.15	-0.45, 0.10	
Difference (95% CI) in CFB [2]		-0.26 (-0.74, 0.22)		0.02 (-0.37, 0.41)	
p-value [3]		0.288		0.905	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	28	44	34	66	
Mean (StdDev)	1.7 (1.33)	1.8 (1.20)	1.8 (1.22)	1.3 (1.22)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	26	43	34	66	
LS Mean (StdErr) [2]	-0.36 (0.214)	-0.42 (0.179)	-0.51 (0.208)	-0.54 (0.157)	
95% CI [2]	-0.79, 0.06	-0.78, -0.06	-0.93, -0.10	-0.85, -0.23	
Difference (95% CI) in CFB [2]		-0.06 (-0.53, 0.42)		-0.02 (-0.48, 0.43)	
p-value [3]		0.813		0.918	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	22	44	34	69	
Mean (StdDev)	1.5 (1.47)	1.6 (1.30)	2.0 (1.27)	1.5 (1.34)	
Median	1.5	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	20	43	34	68	
LS Mean (StdErr) [2]	-0.70 (0.291)	-0.80 (0.233)	-0.39 (0.216)	-0.43 (0.163)	
95% CI [2]	-1.28, -0.12	-1.26, -0.33	-0.82, 0.04	-0.75, -0.10	
Difference (95% CI) in CFB [2]		-0.09 (-0.70, 0.51)		-0.04 (-0.51, 0.43)	
p-value [3]		0.755		0.875	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	26	41	34	68	
Mean (StdDev)	1.4 (1.47)	1.5 (1.23)	2.0 (1.19)	1.3 (1.28)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	25	38	34	67	
LS Mean (StdErr) [2]	-0.82 (0.280)	-0.94 (0.237)	-0.32 (0.226)	-0.62 (0.172)	
95% CI [2]	-1.38, -0.26	-1.42, -0.47	-0.77, 0.13	-0.96, -0.28	
Difference (95% CI) in CFB [2]		-0.13 (-0.75, 0.50)		-0.30 (-0.79, 0.19)	
p-value [3]		0.684		0.228	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	24	44	34	67	
Mean (StdDev)	1.9 (1.45)	1.3 (1.13)	1.9 (1.39)	1.4 (1.27)	
Median	1.5	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-0.22 (0.264)	-1.09 (0.219)	-0.33 (0.240)	-0.55 (0.181)	
95% CI [2]	-0.75, 0.31	-1.53, -0.66	-0.80, 0.15	-0.91, -0.19	
Difference (95% CI) in CFB [2]		-0.87 (-1.46, -0.29)		-0.23 (-0.75, 0.30)	
p-value [3]		0.004		0.393	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	24	44	34	67	
Mean (StdDev)	1.7 (1.43)	1.4 (1.35)	1.9 (1.33)	1.2 (1.28)	
Median	1.5	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-0.24 (0.255)	-0.66 (0.204)	-0.36 (0.223)	-0.65 (0.168)	
95% CI [2]	-0.75, 0.28	-1.07, -0.25	-0.81, 0.08	-0.98, -0.32	
Difference (95% CI) in CFB [2]		-0.43 (-0.97, 0.11)		-0.29 (-0.77, 0.20)	
Hedges'G (95% CI) in CFB		-0.33 (-0.87, 0.18)		-0.21 (-0.64, 0.20)	
p-value [3]		0.116		0.245	
					0.741

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	30	49	35	70	
Mean (StdDev)	2.4 (1.03)	2.5 (1.00)	2.5 (1.01)	2.5 (1.13)	
Median	2.0	3.0	3.0	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	30	51	35	68	
Mean (StdDev)	2.0 (1.22)	1.8 (1.14)	1.9 (0.91)	1.8 (1.14)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	28	48	35	68	
LS Mean (StdErr) [2]	-0.16 (0.193)	-0.73 (0.161)	-0.68 (0.223)	-0.69 (0.173)	
95% CI [2]	-0.55, 0.23	-1.05, -0.41	-1.12, -0.24	-1.04, -0.35	
Difference (95% CI) in CFB [2]		-0.57 (-1.00, -0.14)		-0.02 (-0.50, 0.47)	
p-value [3]		0.009		0.947	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	29	44	34	65	
Mean (StdDev)	1.9 (1.14)	1.7 (0.95)	2.1 (1.10)	1.7 (1.14)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	27	43	34	65	
LS Mean (StdErr) [2]	-0.48 (0.233)	-0.79 (0.196)	-0.45 (0.230)	-0.87 (0.174)	
95% CI [2]	-0.94, -0.01	-1.18, -0.40	-0.90, 0.01	-1.22, -0.53	
Difference (95% CI) in CFB [2]		-0.31 (-0.83, 0.20)		-0.43 (-0.93, 0.07)	
p-value [3]		0.232		0.093	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	22	44	34	69	
Mean (StdDev)	1.7 (1.16)	1.6 (1.02)	2.0 (1.09)	1.7 (1.22)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	20	43	34	68	
LS Mean (StdErr) [2]	-0.78 (0.249)	-1.08 (0.200)	-0.52 (0.231)	-0.86 (0.173)	
95% CI [2]	-1.28, -0.28	-1.48, -0.68	-0.98, -0.07	-1.20, -0.51	
Difference (95% CI) in CFB [2]		-0.30 (-0.82, 0.21)		-0.33 (-0.83, 0.17)	
p-value [3]		0.244		0.191	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	26	41	34	68	
Mean (StdDev)	1.6 (1.39)	1.5 (1.08)	2.0 (0.95)	1.6 (1.19)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	25	38	34	67	
LS Mean (StdErr) [2]	-0.92 (0.301)	-1.23 (0.255)	-0.47 (0.224)	-0.99 (0.170)	
95% CI [2]	-1.52, -0.32	-1.74, -0.72	-0.91, -0.02	-1.32, -0.65	
Difference (95% CI) in CFB [2]		-0.31 (-0.98, 0.36)		-0.52 (-1.01, -0.03)	
p-value [3]		0.357		0.038	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	24	44	34	67	
Mean (StdDev)	1.8 (1.33)	1.3 (1.01)	2.1 (1.01)	1.6 (1.23)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C6D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-0.68 (0.263)	-1.36 (0.218)	-0.45 (0.235)	-0.99 (0.177)	
95% CI [2]	-1.21, -0.15	-1.79, -0.92	-0.92, 0.01	-1.34, -0.64	
Difference (95% CI) in CFB [2]		-0.68 (-1.26, -0.09)		-0.54 (-1.05, -0.03)	
p-value [3]		0.024		0.040	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	24	44	34	67	
Mean (StdDev)	1.7 (1.23)	1.3 (1.22)	2.0 (1.30)	1.6 (1.31)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	23	41	34	66	
LS Mean (StdErr) [2]	-0.45 (0.307)	-1.14 (0.245)	-0.49 (0.265)	-0.95 (0.200)	
95% CI [2]	-1.06, 0.17	-1.63, -0.65	-1.01, 0.04	-1.35, -0.56	
Difference (95% CI) in CFB [2]		-0.69 (-1.34, -0.04)		-0.47 (-1.04, 0.11)	
Hedges'G (95% CI) in CFB		-0.44 (-0.99, 0.07)		-0.29 (-0.72, 0.12)	
p-value [3]		0.036		0.111	
					0.607

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	29	49	35	70	
Mean (StdDev)	2.0 (1.41)	2.2 (1.15)	2.2 (1.12)	2.2 (1.21)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	30	51	35	68	
Mean (StdDev)	1.8 (1.30)	1.8 (1.08)	2.0 (1.18)	1.8 (1.25)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	27	48	35	68	
LS Mean (StdErr) [2]	-0.21 (0.215)	-0.68 (0.178)	-0.09 (0.199)	-0.27 (0.154)	
95% CI [2]	-0.64, 0.22	-1.04, -0.33	-0.48, 0.31	-0.58, 0.04	
Difference (95% CI) in CFB [2]		-0.47 (-0.95, 0.00)		-0.18 (-0.62, 0.25)	
p-value [3]		0.052		0.407	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	29	44	34	66	
Mean (StdDev)	1.6 (1.24)	1.8 (1.04)	2.0 (1.14)	1.5 (1.14)	
Median	1.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	26	43	34	66	
LS Mean (StdErr) [2]	-0.32 (0.215)	-0.58 (0.180)	-0.05 (0.200)	-0.59 (0.151)	
95% CI [2]	-0.75, 0.11	-0.94, -0.22	-0.45, 0.35	-0.89, -0.29	
Difference (95% CI) in CFB [2]		-0.26 (-0.74, 0.21)		-0.54 (-0.98, -0.11)	
p-value [3]		0.275		0.015	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	22	44	34	69	
Mean (StdDev)	1.2 (1.15)	1.7 (1.16)	2.2 (1.17)	1.6 (1.31)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C4D1 CFB					
n	19	43	34	68	
LS Mean (StdErr) [2]	-0.72 (0.307)	-0.73 (0.244)	0.05 (0.213)	-0.58 (0.160)	
95% CI [2]	-1.34, -0.11	-1.22, -0.24	-0.37, 0.47	-0.90, -0.26	
Difference (95% CI) in CFB [2]		-0.00 (-0.64, 0.64)		-0.63 (-1.10, -0.17)	
p-value [3]		0.991		0.008	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	26	41	34	68	
Mean (StdDev)	1.3 (1.09)	1.4 (1.07)	2.0 (1.06)	1.6 (1.20)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C5D1 CFB					
n	24	38	34	67	
LS Mean (StdErr) [2]	-0.57 (0.273)	-0.88 (0.229)	-0.08 (0.217)	-0.62 (0.165)	
95% CI [2]	-1.12, -0.03	-1.34, -0.42	-0.51, 0.35	-0.94, -0.29	
Difference (95% CI) in CFB [2]		-0.31 (-0.92, 0.30)		-0.53 (-1.01, -0.06)	
p-value [3]		0.314		0.028	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	24	44	34	67	
Mean (StdDev)	1.5 (1.22)	1.3 (1.11)	2.0 (1.17)	1.6 (1.28)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	22	41	34	66	
LS Mean (StdErr) [2]	-0.43 (0.299)	-1.11 (0.246)	-0.07 (0.216)	-0.64 (0.163)	
95% CI [2]	-1.03, 0.17	-1.60, -0.62	-0.50, 0.36	-0.97, -0.32	
Difference (95% CI) in CFB [2]		-0.68 (-1.35, -0.02)		-0.57 (-1.04, -0.10)	
p-value [3]		0.045		0.018	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	24	44	34	67	
Mean (StdDev)	1.4 (1.06)	1.5 (1.13)	2.0 (1.22)	1.6 (1.35)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C7D1 CFB					
n	22	41	34	66	
LS Mean (StdErr) [2]	-0.27 (0.293)	-0.70 (0.232)	-0.01 (0.241)	-0.50 (0.181)	
95% CI [2]	-0.85, 0.32	-1.16, -0.23	-0.48, 0.47	-0.86, -0.14	
Difference (95% CI) in CFB [2]		-0.43 (-1.05, 0.19)		-0.50 (-1.02, 0.03)	
Hedges'G (95% CI) in CFB		-0.29 (-0.84, 0.23)		-0.34 (-0.77, 0.07)	
p-value [3]		0.169		0.064	
					0.903

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-reg-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-cou-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-cou-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-cou-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-cou-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching			
	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-cou-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-cou-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-cou-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling			
	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea			
	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-cou-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue			
	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain						
	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain

	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-cou-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating						
	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-cou-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-cou-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating			
	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-cou-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-cou-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work						
	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-cou-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work			
	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity						
	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-cou-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep			
	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity						
	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity

	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time						
	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time			
	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-cou-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day						
	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-cou-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day			
	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-cou-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices			
	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms						
	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms			
	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction			
	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
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[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment			
	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-cou-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-cou-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-cou-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis						
	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis			
	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation			
	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-cou-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-cou-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-cou-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-cou-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-cou-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-cou-a.sas Date: 16:04/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	21	35	44	84	
Mean (StdDev)	2.0 (1.24)	1.8 (0.89)	3.1 (0.89)	2.6 (1.10)	
Median	2.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 3	1, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	21	35	44	84	
Mean (StdDev)	2.0 (1.00)	1.4 (0.88)	2.5 (1.02)	1.8 (0.90)	
Median	2.0	1.0	2.5	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C2D1 CFB					
n	20	34	43	82	
LS Mean (StdErr) [2]	-0.23 (0.221)	-0.43 (0.153)	-0.59 (0.187)	-0.77 (0.152)	
95% CI [2]	-0.68, 0.21	-0.73, -0.12	-0.96, -0.22	-1.07, -0.47	
Difference (95% CI) in CFB [2]		-0.19 (-0.66, 0.27)		-0.18 (-0.62, 0.25)	
p-value [3]		0.412		0.406	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	18	33	45	77	
Mean (StdDev)	1.5 (1.10)	1.2 (0.86)	2.4 (1.05)	1.6 (0.94)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C3D1 CFB					
n	17	33	44	76	
LS Mean (StdErr) [2]	-0.61 (0.276)	-0.61 (0.182)	-0.70 (0.194)	-0.87 (0.161)	
95% CI [2]	-1.16, -0.05	-0.98, -0.25	-1.08, -0.31	-1.19, -0.55	
Difference (95% CI) in CFB [2]		-0.01 (-0.60, 0.58)		-0.17 (-0.63, 0.28)	
p-value [3]		0.974		0.450	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	17	33	39	80	
Mean (StdDev)	1.9 (1.25)	1.1 (0.75)	2.4 (0.99)	1.6 (1.09)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 3	1, 4	0, 4	
C4D1 CFB					
n	16	32	38	79	
LS Mean (StdErr) [2]	-0.42 (0.301)	-0.93 (0.207)	-0.60 (0.214)	-0.95 (0.164)	
95% CI [2]	-1.02, 0.19	-1.34, -0.51	-1.02, -0.17	-1.27, -0.62	
Difference (95% CI) in CFB [2]		-0.51 (-1.14, 0.11)		-0.35 (-0.83, 0.13)	
p-value [3]		0.105		0.155	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	31	41	77	
Mean (StdDev)	2.1 (1.31)	1.2 (0.93)	2.4 (1.14)	1.4 (0.98)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C5D1 CFB					
n	18	29	41	75	
LS Mean (StdErr) [2]	-0.14 (0.317)	-0.78 (0.223)	-0.67 (0.207)	-1.06 (0.164)	
95% CI [2]	-0.78, 0.49	-1.23, -0.33	-1.08, -0.27	-1.38, -0.73	
Difference (95% CI) in CFB [2]		-0.64 (-1.32, 0.04)		-0.38 (-0.86, 0.10)	
p-value [3]		0.066		0.116	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	19	33	39	78	
Mean (StdDev)	1.8 (1.23)	1.2 (0.86)	2.4 (1.16)	1.6 (1.09)	
Median	1.0	1.0	3.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C6D1 CFB					
n	18	31	39	76	
LS Mean (StdErr) [2]	-0.42 (0.261)	-0.69 (0.182)	-0.78 (0.217)	-1.05 (0.169)	
95% CI [2]	-0.95, 0.10	-1.06, -0.33	-1.21, -0.35	-1.39, -0.72	
Difference (95% CI) in CFB [2]		-0.27 (-0.82, 0.29)		-0.27 (-0.77, 0.23)	
p-value [3]		0.339		0.292	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	18	35	40	76	
Mean (StdDev)	2.0 (1.24)	1.3 (0.89)	2.5 (1.08)	1.3 (0.99)	
Median	2.0	1.0	2.5	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	17	33	40	74	
LS Mean (StdErr) [2]	-0.31 (0.238)	-0.69 (0.162)	-0.64 (0.205)	-1.13 (0.162)	
95% CI [2]	-0.79, 0.17	-1.02, -0.37	-1.05, -0.24	-1.45, -0.80	
Difference (95% CI) in CFB [2]		-0.39 (-0.89, 0.11)		-0.48 (-0.95, -0.02)	
Hedges'G (95% CI) in CFB		-0.40 (-1.03, 0.18)		-0.35 (-0.75, 0.03)	
p-value [3]		0.126		0.043	
					0.938

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	21	35	44	84	
Mean (StdDev)	2.2 (1.09)	1.6 (1.01)	2.6 (1.18)	2.3 (1.12)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	21	35	44	84	
Mean (StdDev)	2.0 (1.22)	1.3 (0.83)	2.3 (1.07)	1.5 (1.05)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C2D1 CFB					
n	20	34	43	82	
LS Mean (StdErr) [2]	-0.15 (0.227)	-0.27 (0.157)	-0.31 (0.202)	-0.82 (0.163)	
95% CI [2]	-0.60, 0.31	-0.58, 0.05	-0.71, 0.09	-1.15, -0.50	
Difference (95% CI) in CFB [2]		-0.12 (-0.60, 0.36)		-0.51 (-0.98, -0.04)	
p-value [3]		0.624		0.032	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	18	33	45	77	
Mean (StdDev)	1.9 (1.13)	1.2 (0.93)	2.2 (1.26)	1.5 (1.02)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C3D1 CFB					
n	17	33	44	76	
LS Mean (StdErr) [2]	-0.39 (0.286)	-0.32 (0.190)	-0.40 (0.205)	-0.85 (0.169)	
95% CI [2]	-0.96, 0.19	-0.70, 0.06	-0.81, 0.01	-1.18, -0.51	
Difference (95% CI) in CFB [2]		0.07 (-0.54, 0.68)		-0.45 (-0.93, 0.03)	
p-value [3]		0.827		0.067	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	17	33	39	80	
Mean (StdDev)	2.1 (1.25)	1.1 (0.66)	2.2 (0.99)	1.4 (1.15)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 2	0, 4	0, 4	
C4D1 CFB					
n	16	32	38	79	
LS Mean (StdErr) [2]	-0.19 (0.281)	-0.54 (0.193)	-0.33 (0.214)	-0.91 (0.165)	
95% CI [2]	-0.76, 0.37	-0.92, -0.15	-0.76, 0.09	-1.23, -0.58	
Difference (95% CI) in CFB [2]		-0.34 (-0.92, 0.24)		-0.57 (-1.06, -0.09)	
p-value [3]		0.243		0.020	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	31	41	77	
Mean (StdDev)	1.9 (1.27)	1.2 (0.86)	2.2 (1.28)	1.4 (1.02)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C5D1 CFB					
n	18	29	41	75	
LS Mean (StdErr) [2]	-0.22 (0.316)	-0.35 (0.222)	-0.37 (0.204)	-0.85 (0.162)	
95% CI [2]	-0.86, 0.41	-0.79, 0.10	-0.77, 0.04	-1.17, -0.53	
Difference (95% CI) in CFB [2]		-0.12 (-0.80, 0.56)		-0.49 (-0.96, -0.01)	
p-value [3]		0.720		0.043	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	19	33	39	78	
Mean (StdDev)	1.9 (1.13)	1.3 (0.94)	2.2 (1.20)	1.6 (1.14)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	18	31	39	76	
LS Mean (StdErr) [2]	-0.33 (0.279)	-0.32 (0.194)	-0.27 (0.217)	-0.84 (0.169)	
95% CI [2]	-0.90, 0.23	-0.71, 0.07	-0.70, 0.15	-1.17, -0.50	
Difference (95% CI) in CFB [2]		0.01 (-0.58, 0.61)		-0.56 (-1.06, -0.06)	
p-value [3]		0.961		0.028	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	18	35	40	76	
Mean (StdDev)	2.1 (1.18)	1.4 (1.03)	2.2 (1.21)	1.4 (1.12)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	17	33	40	74	
LS Mean (StdErr) [2]	-0.14 (0.292)	-0.26 (0.198)	-0.31 (0.222)	-0.81 (0.175)	
95% CI [2]	-0.72, 0.45	-0.66, 0.14	-0.75, 0.13	-1.16, -0.46	
Difference (95% CI) in CFB [2]		-0.12 (-0.73, 0.49)		-0.50 (-1.00, 0.01)	
Hedges'G (95% CI) in CFB		-0.10 (-0.71, 0.49)		-0.34 (-0.73, 0.05)	
p-value [3]		0.693		0.054	
					0.476

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	21	35	44	84	
Mean (StdDev)	1.6 (1.03)	1.8 (1.09)	2.6 (1.04)	2.6 (0.98)	
Median	1.0	2.0	3.0	3.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	21	35	44	84	
Mean (StdDev)	1.6 (0.98)	1.4 (1.06)	2.3 (1.07)	2.0 (1.02)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C2D1 CFB					
n	20	34	43	82	
LS Mean (StdErr) [2]	-0.17 (0.251)	-0.39 (0.174)	-0.27 (0.169)	-0.48 (0.137)	
95% CI [2]	-0.68, 0.33	-0.74, -0.04	-0.60, 0.07	-0.75, -0.21	
Difference (95% CI) in CFB [2]		-0.22 (-0.75, 0.32)		-0.21 (-0.60, 0.18)	
p-value [3]		0.419		0.284	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	18	33	45	77	
Mean (StdDev)	1.4 (0.92)	1.6 (1.09)	2.2 (1.01)	1.8 (1.10)	
Median	1.5	1.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C3D1 CFB					
n	17	33	44	76	
LS Mean (StdErr) [2]	-0.12 (0.304)	-0.21 (0.201)	-0.39 (0.182)	-0.72 (0.151)	
95% CI [2]	-0.73, 0.50	-0.62, 0.19	-0.76, -0.03	-1.02, -0.42	
Difference (95% CI) in CFB [2]		-0.10 (-0.74, 0.55)		-0.32 (-0.75, 0.10)	
p-value [3]		0.769		0.137	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	17	33	39	80	
Mean (StdDev)	1.4 (0.86)	1.5 (1.03)	2.4 (1.10)	1.9 (1.01)	
Median	1.0	1.0	3.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C4D1 CFB					
n	16	32	38	79	
LS Mean (StdErr) [2]	-0.27 (0.319)	-0.27 (0.219)	-0.18 (0.198)	-0.73 (0.152)	
95% CI [2]	-0.92, 0.37	-0.72, 0.17	-0.57, 0.21	-1.03, -0.43	
Difference (95% CI) in CFB [2]		0.00 (-0.66, 0.66)		-0.55 (-1.00, -0.10)	
p-value [3]		>0.999		0.016	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	31	41	77	
Mean (StdDev)	1.5 (1.22)	1.3 (0.94)	2.3 (1.17)	1.9 (1.09)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C5D1 CFB					
n	18	29	41	75	
LS Mean (StdErr) [2]	-0.18 (0.389)	-0.37 (0.274)	-0.31 (0.192)	-0.70 (0.152)	
95% CI [2]	-0.97, 0.60	-0.92, 0.18	-0.69, 0.07	-1.00, -0.40	
Difference (95% CI) in CFB [2]		-0.18 (-1.02, 0.66)		-0.39 (-0.83, 0.06)	
p-value [3]		0.660		0.086	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	19	33	39	78	
Mean (StdDev)	1.7 (1.16)	1.1 (0.97)	2.0 (1.21)	1.9 (1.10)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C6D1 CFB					
n	18	31	39	76	
LS Mean (StdErr) [2]	0.05 (0.319)	-0.61 (0.222)	-0.47 (0.202)	-0.63 (0.157)	
95% CI [2]	-0.59, 0.69	-1.06, -0.16	-0.87, -0.07	-0.94, -0.32	
Difference (95% CI) in CFB [2]		-0.66 (-1.34, 0.02)		-0.16 (-0.62, 0.31)	
p-value [3]		0.055		0.510	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	18	35	40	76	
Mean (StdDev)	1.3 (1.03)	1.3 (1.06)	2.1 (1.09)	1.8 (1.11)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C7D1 CFB					
n	17	33	40	74	
LS Mean (StdErr) [2]	-0.32 (0.371)	-0.47 (0.252)	-0.41 (0.207)	-0.75 (0.164)	
95% CI [2]	-1.07, 0.43	-0.98, 0.03	-0.82, 0.00	-1.07, -0.43	
Difference (95% CI) in CFB [2]		-0.15 (-0.93, 0.63)		-0.34 (-0.82, 0.13)	
Hedges'G (95% CI) in CFB		-0.10 (-0.71, 0.49)		-0.25 (-0.64, 0.14)	
p-value [3]		0.694		0.152	
					0.742

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	21	35	44	84	
Mean (StdDev)	1.6 (1.07)	2.0 (0.98)	2.3 (1.20)	2.2 (1.30)	
Median	2.0	2.0	2.5	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	21	34	44	84	
Mean (StdDev)	1.5 (1.17)	1.3 (1.07)	1.8 (1.17)	1.6 (1.15)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	20	33	43	82	
LS Mean (StdErr) [2]	0.22 (0.245)	-0.48 (0.174)	-0.51 (0.201)	-0.55 (0.162)	
95% CI [2]	-0.28, 0.71	-0.83, -0.13	-0.91, -0.11	-0.87, -0.23	
Difference (95% CI) in CFB [2]		-0.70 (-1.21, -0.19)		-0.04 (-0.51, 0.42)	
p-value [3]		0.009		0.854	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	18	33	45	77	
Mean (StdDev)	1.4 (1.10)	1.6 (1.25)	1.9 (1.35)	1.5 (1.11)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	17	33	44	76	
LS Mean (StdErr) [2]	0.17 (0.272)	-0.31 (0.180)	-0.42 (0.220)	-0.69 (0.182)	
95% CI [2]	-0.38, 0.72	-0.67, 0.06	-0.85, 0.02	-1.05, -0.33	
Difference (95% CI) in CFB [2]		-0.48 (-1.06, 0.10)		-0.27 (-0.79, 0.24)	
p-value [3]		0.105		0.293	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	17	33	39	80	
Mean (StdDev)	1.5 (1.12)	1.4 (1.00)	1.9 (1.24)	1.6 (1.26)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	16	32	38	79	
LS Mean (StdErr) [2]	0.04 (0.249)	-0.56 (0.171)	-0.55 (0.222)	-0.60 (0.171)	
95% CI [2]	-0.47, 0.54	-0.91, -0.22	-0.99, -0.11	-0.93, -0.26	
Difference (95% CI) in CFB [2]		-0.60 (-1.11, -0.08)		-0.04 (-0.55, 0.46)	
p-value [3]		0.024		0.861	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	31	41	77	
Mean (StdDev)	1.5 (1.07)	1.3 (1.09)	2.0 (1.09)	1.5 (1.19)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	18	29	41	75	
LS Mean (StdErr) [2]	0.28 (0.309)	-0.57 (0.217)	-0.37 (0.214)	-0.75 (0.170)	
95% CI [2]	-0.34, 0.91	-1.01, -0.14	-0.79, 0.06	-1.08, -0.41	
Difference (95% CI) in CFB [2]		-0.86 (-1.52, -0.19)		-0.38 (-0.87, 0.12)	
p-value [3]		0.013		0.132	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	19	33	39	78	
Mean (StdDev)	1.5 (1.07)	1.4 (1.17)	1.9 (1.24)	1.4 (1.14)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	18	31	39	76	
LS Mean (StdErr) [2]	0.16 (0.309)	-0.52 (0.215)	-0.43 (0.216)	-0.73 (0.168)	
95% CI [2]	-0.46, 0.78	-0.96, -0.09	-0.85, 0.00	-1.07, -0.40	
Difference (95% CI) in CFB [2]		-0.68 (-1.34, -0.03)		-0.31 (-0.81, 0.19)	
p-value [3]		0.042		0.222	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	18	35	40	76	
Mean (StdDev)	1.6 (0.98)	1.5 (1.15)	1.8 (1.15)	1.4 (1.29)	
Median	1.5	1.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C7D1 CFB					
n	17	33	40	74	
LS Mean (StdErr) [2]	0.28 (0.251)	-0.42 (0.170)	-0.43 (0.228)	-0.64 (0.181)	
95% CI [2]	-0.22, 0.79	-0.76, -0.08	-0.88, 0.02	-1.00, -0.28	
Difference (95% CI) in CFB [2]		-0.71 (-1.23, -0.18)		-0.21 (-0.73, 0.31)	
Hedges'G (95% CI) in CFB		-0.70 (-1.35, -0.11)		-0.14 (-0.53, 0.25)	
p-value [3]		0.010		0.425	
					0.214

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	21	35	44	84	
Mean (StdDev)	2.7 (0.96)	2.9 (0.96)	3.3 (0.83)	3.4 (0.78)	
Median	3.0	3.0	4.0	4.0	
Min, Max	1, 4	1, 4	1, 4	1, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	21	35	44	84	
Mean (StdDev)	2.5 (0.87)	2.3 (1.10)	2.9 (0.97)	2.9 (1.02)	
Median	3.0	2.0	3.0	3.0	
Min, Max	1, 4	0, 4	1, 4	0, 4	
C2D1 CFB					
n	20	34	43	82	
LS Mean (StdErr) [2]	-0.04 (0.246)	-0.53 (0.170)	-0.45 (0.158)	-0.54 (0.128)	
95% CI [2]	-0.53, 0.46	-0.87, -0.19	-0.77, -0.14	-0.80, -0.29	
Difference (95% CI) in CFB [2]		-0.50 (-1.02, 0.03)		-0.09 (-0.46, 0.27)	
p-value [3]		0.062		0.620	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	18	33	45	77	
Mean (StdDev)	2.5 (0.99)	2.1 (0.99)	2.8 (1.15)	2.7 (1.09)	
Median	2.5	2.0	3.0	3.0	
Min, Max	1, 4	1, 4	0, 4	0, 4	
C3D1 CFB					
n	17	33	44	76	
LS Mean (StdErr) [2]	-0.09 (0.272)	-0.77 (0.180)	-0.56 (0.182)	-0.68 (0.151)	
95% CI [2]	-0.63, 0.46	-1.13, -0.41	-0.92, -0.20	-0.98, -0.38	
Difference (95% CI) in CFB [2]		-0.69 (-1.27, -0.11)		-0.11 (-0.54, 0.31)	
p-value [3]		0.022		0.597	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	17	33	39	80	
Mean (StdDev)	2.4 (1.17)	2.3 (1.10)	2.9 (1.07)	2.6 (1.11)	
Median	2.0	2.0	3.0	3.0	
Min, Max	1, 4	1, 4	1, 4	0, 4	
C4D1 CFB					
n	16	32	38	79	
LS Mean (StdErr) [2]	-0.22 (0.296)	-0.58 (0.203)	-0.57 (0.202)	-0.80 (0.155)	
95% CI [2]	-0.82, 0.37	-0.99, -0.17	-0.97, -0.17	-1.11, -0.50	
Difference (95% CI) in CFB [2]		-0.35 (-0.97, 0.26)		-0.23 (-0.69, 0.23)	
p-value [3]		0.251		0.321	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	31	41	77	
Mean (StdDev)	2.4 (1.17)	2.1 (1.11)	2.9 (1.22)	2.5 (1.15)	
Median	3.0	2.0	3.0	3.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	18	29	41	75	
LS Mean (StdErr) [2]	-0.08 (0.256)	-0.79 (0.180)	-0.56 (0.201)	-0.84 (0.159)	
95% CI [2]	-0.60, 0.43	-1.15, -0.43	-0.96, -0.17	-1.16, -0.53	
Difference (95% CI) in CFB [2]		-0.71 (-1.26, -0.16)		-0.28 (-0.74, 0.19)	
p-value [3]		0.013		0.237	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	19	33	39	78	
Mean (StdDev)	2.6 (1.02)	2.0 (1.10)	2.7 (1.15)	2.5 (1.20)	
Median	3.0	2.0	3.0	3.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	18	31	39	76	
LS Mean (StdErr) [2]	-0.19 (0.270)	-0.88 (0.188)	-0.77 (0.209)	-0.94 (0.163)	
95% CI [2]	-0.73, 0.36	-1.26, -0.50	-1.18, -0.35	-1.26, -0.61	
Difference (95% CI) in CFB [2]		-0.69 (-1.27, -0.12)		-0.17 (-0.65, 0.31)	
p-value [3]		0.019		0.490	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	18	35	40	76	
Mean (StdDev)	2.4 (1.04)	2.1 (1.02)	2.7 (1.11)	2.5 (1.15)	
Median	2.0	2.0	3.0	3.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	17	33	40	74	
LS Mean (StdErr) [2]	-0.16 (0.256)	-0.65 (0.173)	-0.67 (0.204)	-0.88 (0.162)	
95% CI [2]	-0.68, 0.35	-1.00, -0.30	-1.07, -0.26	-1.20, -0.56	
Difference (95% CI) in CFB [2]		-0.49 (-1.02, 0.05)		-0.22 (-0.68, 0.25)	
Hedges'G (95% CI) in CFB		-0.47 (-1.10, 0.11)		-0.16 (-0.55, 0.23)	
p-value [3]		0.073		0.360	
					0.572

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	21	35	44	84	
Mean (StdDev)	1.5 (1.17)	2.0 (1.11)	2.4 (1.00)	2.3 (1.01)	
Median	1.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	21	35	44	84	
Mean (StdDev)	1.5 (1.21)	1.7 (0.96)	2.2 (0.97)	1.9 (1.00)	
Median	1.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	20	34	43	82	
LS Mean (StdErr) [2]	-0.07 (0.233)	-0.30 (0.161)	-0.21 (0.155)	-0.32 (0.125)	
95% CI [2]	-0.54, 0.40	-0.63, 0.02	-0.52, 0.09	-0.56, -0.07	
Difference (95% CI) in CFB [2]		-0.24 (-0.73, 0.26)		-0.10 (-0.46, 0.26)	
p-value [3]		0.342		0.571	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	18	33	45	77	
Mean (StdDev)	1.3 (1.07)	1.5 (0.79)	2.1 (1.05)	1.7 (1.03)	
Median	1.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C3D1 CFB					
n	17	33	44	76	
LS Mean (StdErr) [2]	-0.08 (0.299)	-0.59 (0.198)	-0.30 (0.171)	-0.50 (0.141)	
95% CI [2]	-0.69, 0.52	-0.99, -0.19	-0.64, 0.04	-0.78, -0.22	
Difference (95% CI) in CFB [2]		-0.50 (-1.14, 0.13)		-0.19 (-0.59, 0.21)	
p-value [3]		0.118		0.344	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	17	33	39	80	
Mean (StdDev)	1.5 (1.23)	1.5 (1.00)	2.2 (1.12)	1.9 (1.20)	
Median	1.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C4D1 CFB					
n	16	32	38	79	
LS Mean (StdErr) [2]	0.09 (0.344)	-0.41 (0.236)	-0.29 (0.187)	-0.33 (0.143)	
95% CI [2]	-0.61, 0.78	-0.89, 0.06	-0.66, 0.08	-0.61, -0.04	
Difference (95% CI) in CFB [2]		-0.50 (-1.21, 0.21)		-0.04 (-0.46, 0.39)	
p-value [3]		0.164		0.868	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	31	41	77	
Mean (StdDev)	1.4 (1.21)	1.4 (0.95)	2.2 (1.17)	1.9 (1.15)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	18	29	41	75	
LS Mean (StdErr) [2]	-0.01 (0.307)	-0.44 (0.216)	-0.27 (0.174)	-0.40 (0.138)	
95% CI [2]	-0.63, 0.60	-0.88, -0.01	-0.61, 0.08	-0.67, -0.12	
Difference (95% CI) in CFB [2]		-0.43 (-1.09, 0.24)		-0.13 (-0.53, 0.27)	
p-value [3]		0.202		0.519	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	19	33	39	78	
Mean (StdDev)	1.4 (1.12)	1.3 (0.85)	2.1 (1.00)	1.8 (1.24)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C6D1 CFB					
n	18	31	39	76	
LS Mean (StdErr) [2]	-0.11 (0.268)	-0.61 (0.186)	-0.32 (0.178)	-0.42 (0.138)	
95% CI [2]	-0.65, 0.43	-0.99, -0.24	-0.67, 0.03	-0.69, -0.14	
Difference (95% CI) in CFB [2]		-0.50 (-1.07, 0.07)		-0.10 (-0.51, 0.31)	
p-value [3]		0.082		0.634	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	18	35	40	76	
Mean (StdDev)	1.1 (0.90)	1.4 (0.91)	2.1 (1.05)	1.7 (1.17)	
Median	1.0	1.0	2.0	1.5	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C7D1 CFB					
n	17	33	40	74	
LS Mean (StdErr) [2]	-0.25 (0.248)	-0.42 (0.168)	-0.33 (0.181)	-0.52 (0.143)	
95% CI [2]	-0.75, 0.25	-0.76, -0.08	-0.69, 0.03	-0.81, -0.24	
Difference (95% CI) in CFB [2]		-0.17 (-0.69, 0.35)		-0.19 (-0.60, 0.22)	
Hedges'G (95% CI) in CFB		-0.17 (-0.78, 0.42)		-0.16 (-0.55, 0.23)	
p-value [3]		0.515		0.366	
					0.898

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	21	35	44	84	
Mean (StdDev)	2.0 (1.24)	2.2 (1.26)	3.1 (0.94)	3.1 (0.98)	
Median	2.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	21	34	44	84	
Mean (StdDev)	2.0 (1.05)	1.9 (1.15)	2.5 (1.09)	2.3 (1.06)	
Median	2.0	2.0	2.5	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	20	33	43	82	
LS Mean (StdErr) [2]	0.14 (0.210)	-0.19 (0.149)	-0.63 (0.159)	-0.69 (0.129)	
95% CI [2]	-0.28, 0.56	-0.49, 0.11	-0.94, -0.31	-0.94, -0.43	
Difference (95% CI) in CFB [2]		-0.33 (-0.77, 0.11)		-0.06 (-0.43, 0.31)	
p-value [3]		0.134		0.742	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	18	33	45	77	
Mean (StdDev)	2.1 (1.02)	1.7 (1.05)	2.3 (1.19)	2.3 (1.24)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	17	33	44	76	
LS Mean (StdErr) [2]	0.08 (0.311)	-0.63 (0.206)	-0.81 (0.177)	-0.66 (0.146)	
95% CI [2]	-0.55, 0.70	-1.04, -0.21	-1.16, -0.46	-0.95, -0.37	
Difference (95% CI) in CFB [2]		-0.70 (-1.37, -0.04)		0.15 (-0.26, 0.56)	
p-value [3]		0.038		0.470	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	17	33	39	80	
Mean (StdDev)	2.1 (1.03)	1.9 (1.04)	2.6 (1.19)	2.3 (1.28)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	16	32	38	79	
LS Mean (StdErr) [2]	0.18 (0.402)	-0.51 (0.276)	-0.62 (0.195)	-0.69 (0.150)	
95% CI [2]	-0.63, 0.99	-1.07, 0.05	-1.01, -0.23	-0.99, -0.40	
Difference (95% CI) in CFB [2]		-0.70 (-1.53, 0.14)		-0.08 (-0.52, 0.37)	
p-value [3]		0.100		0.733	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	31	41	77	
Mean (StdDev)	1.9 (1.13)	1.8 (1.09)	2.7 (1.05)	2.5 (1.19)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	18	29	41	75	
LS Mean (StdErr) [2]	-0.09 (0.285)	-0.57 (0.200)	-0.38 (0.184)	-0.56 (0.146)	
95% CI [2]	-0.66, 0.48	-0.97, -0.17	-0.75, -0.02	-0.85, -0.27	
Difference (95% CI) in CFB [2]		-0.48 (-1.09, 0.14)		-0.18 (-0.61, 0.25)	
p-value [3]		0.124		0.402	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	19	33	39	78	
Mean (StdDev)	2.2 (1.27)	1.6 (1.00)	2.6 (1.19)	2.3 (1.22)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	18	31	39	76	
LS Mean (StdErr) [2]	0.23 (0.277)	-0.74 (0.192)	-0.55 (0.202)	-0.66 (0.158)	
95% CI [2]	-0.32, 0.79	-1.13, -0.35	-0.95, -0.15	-0.98, -0.35	
Difference (95% CI) in CFB [2]		-0.97 (-1.56, -0.38)		-0.11 (-0.58, 0.35)	
p-value [3]		0.002		0.632	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	18	35	40	76	
Mean (StdDev)	2.2 (1.31)	1.9 (1.14)	2.3 (1.15)	2.3 (1.17)	
Median	3.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	17	33	40	74	
LS Mean (StdErr) [2]	0.52 (0.248)	-0.13 (0.168)	-0.82 (0.198)	-0.79 (0.156)	
95% CI [2]	0.02, 1.02	-0.47, 0.21	-1.21, -0.43	-1.10, -0.48	
Difference (95% CI) in CFB [2]		-0.65 (-1.17, -0.13)		0.03 (-0.42, 0.48)	
Hedges'G (95% CI) in CFB		-0.65 (-1.30, -0.07)		0.02 (-0.37, 0.41)	
p-value [3]		0.015		0.901	
					0.143

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	21	35	44	84	
Mean (StdDev)	1.7 (0.72)	2.2 (1.06)	2.6 (1.19)	2.9 (1.02)	
Median	2.0	2.0	3.0	3.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	21	35	43	84	
Mean (StdDev)	1.9 (0.91)	1.6 (0.98)	2.2 (1.32)	2.3 (1.17)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	20	34	42	82	
LS Mean (StdErr) [2]	0.46 (0.243)	-0.43 (0.168)	-0.40 (0.149)	-0.67 (0.119)	
95% CI [2]	-0.03, 0.94	-0.77, -0.09	-0.70, -0.11	-0.91, -0.43	
Difference (95% CI) in CFB [2]		-0.88 (-1.40, -0.37)		-0.27 (-0.61, 0.08)	
p-value [3]		0.001		0.125	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	18	33	45	77	
Mean (StdDev)	1.8 (1.06)	1.4 (1.03)	2.3 (1.21)	2.1 (1.18)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C3D1 CFB					
n	17	33	44	76	
LS Mean (StdErr) [2]	0.32 (0.263)	-0.62 (0.174)	-0.29 (0.138)	-0.75 (0.115)	
95% CI [2]	-0.21, 0.85	-0.97, -0.27	-0.56, -0.01	-0.98, -0.53	
Difference (95% CI) in CFB [2]		-0.94 (-1.50, -0.38)		-0.47 (-0.79, -0.14)	
p-value [3]		0.001		0.005	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	17	33	39	80	
Mean (StdDev)	1.6 (1.11)	1.5 (0.97)	2.3 (1.15)	2.2 (1.21)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	16	32	38	79	
LS Mean (StdErr) [2]	0.40 (0.270)	-0.43 (0.186)	-0.36 (0.175)	-0.67 (0.135)	
95% CI [2]	-0.15, 0.94	-0.81, -0.06	-0.71, -0.02	-0.94, -0.41	
Difference (95% CI) in CFB [2]		-0.83 (-1.39, -0.27)		-0.31 (-0.71, 0.09)	
p-value [3]		0.005		0.126	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	31	41	77	
Mean (StdDev)	1.6 (1.12)	1.5 (0.96)	2.3 (1.20)	2.1 (1.20)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	18	29	41	75	
LS Mean (StdErr) [2]	0.24 (0.224)	-0.48 (0.158)	-0.30 (0.183)	-0.80 (0.145)	
95% CI [2]	-0.21, 0.69	-0.79, -0.16	-0.66, 0.07	-1.09, -0.52	
Difference (95% CI) in CFB [2]		-0.72 (-1.20, -0.24)		-0.51 (-0.93, -0.08)	
p-value [3]		0.004		0.019	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	19	33	39	78	
Mean (StdDev)	1.7 (1.24)	1.3 (1.02)	2.2 (1.18)	2.1 (1.27)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C6D1 CFB					
n	18	31	39	76	
LS Mean (StdErr) [2]	0.29 (0.275)	-0.71 (0.191)	-0.49 (0.184)	-0.83 (0.143)	
95% CI [2]	-0.26, 0.84	-1.09, -0.33	-0.85, -0.12	-1.11, -0.54	
Difference (95% CI) in CFB [2]		-1.00 (-1.59, -0.42)		-0.34 (-0.77, 0.08)	
p-value [3]		0.001		0.114	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	18	35	40	76	
Mean (StdDev)	1.6 (0.85)	1.5 (1.12)	2.3 (1.26)	1.9 (1.30)	
Median	2.0	1.0	3.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C7D1 CFB					
n	17	33	40	74	
LS Mean (StdErr) [2]	0.31 (0.260)	-0.51 (0.176)	-0.31 (0.181)	-0.96 (0.143)	
95% CI [2]	-0.21, 0.83	-0.86, -0.16	-0.67, 0.04	-1.25, -0.68	
Difference (95% CI) in CFB [2]		-0.82 (-1.37, -0.28)		-0.65 (-1.06, -0.23)	
Hedges'G (95% CI) in CFB		-0.79 (-1.44, -0.20)		-0.54 (-0.94, -0.15)	
p-value [3]		0.004		0.002	
					0.893

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	21	35	44	84	
Mean (StdDev)	1.8 (1.33)	1.9 (1.48)	2.2 (1.34)	2.3 (1.43)	
Median	2.0	2.0	2.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	21	35	44	84	
Mean (StdDev)	1.2 (1.34)	1.3 (1.41)	1.9 (1.38)	1.8 (1.38)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	20	34	43	82	
LS Mean (StdErr) [2]	-0.14 (0.397)	-0.31 (0.275)	-0.43 (0.222)	-0.60 (0.179)	
95% CI [2]	-0.94, 0.65	-0.86, 0.24	-0.87, 0.01	-0.96, -0.25	
Difference (95% CI) in CFB [2]		-0.17 (-1.01, 0.67)		-0.17 (-0.68, 0.34)	
p-value [3]		0.686		0.512	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	18	33	45	76	
Mean (StdDev)	1.6 (1.20)	1.3 (1.28)	1.8 (1.37)	1.7 (1.42)	
Median	1.5	1.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C3D1 CFB					
n	17	33	44	76	
LS Mean (StdErr) [2]	0.28 (0.405)	-0.34 (0.268)	-0.49 (0.231)	-0.70 (0.191)	
95% CI [2]	-0.54, 1.09	-0.88, 0.20	-0.94, -0.03	-1.08, -0.32	
Difference (95% CI) in CFB [2]		-0.62 (-1.48, 0.24)		-0.21 (-0.75, 0.33)	
p-value [3]		0.156		0.435	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	17	33	39	80	
Mean (StdDev)	1.8 (1.30)	1.4 (1.17)	1.9 (1.19)	1.6 (1.38)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	16	32	38	79	
LS Mean (StdErr) [2]	0.39 (0.426)	-0.21 (0.292)	-0.45 (0.253)	-0.85 (0.195)	
95% CI [2]	-0.47, 1.24	-0.80, 0.38	-0.95, 0.05	-1.23, -0.46	
Difference (95% CI) in CFB [2]		-0.60 (-1.48, 0.28)		-0.39 (-0.97, 0.18)	
p-value [3]		0.179		0.178	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	32	40	77	
Mean (StdDev)	1.6 (1.17)	1.3 (1.18)	2.1 (1.22)	1.5 (1.36)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C5D1 CFB					
n	18	30	40	75	
LS Mean (StdErr) [2]	0.18 (0.441)	-0.36 (0.308)	-0.28 (0.231)	-1.01 (0.182)	
95% CI [2]	-0.70, 1.07	-0.98, 0.26	-0.74, 0.18	-1.37, -0.65	
Difference (95% CI) in CFB [2]		-0.54 (-1.49, 0.40)		-0.73 (-1.27, -0.20)	
p-value [3]		0.254		0.008	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	19	33	39	78	
Mean (StdDev)	1.8 (1.23)	1.3 (1.22)	2.0 (1.31)	1.6 (1.38)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	18	31	39	76	
LS Mean (StdErr) [2]	0.27 (0.346)	-0.37 (0.240)	-0.33 (0.257)	-0.78 (0.200)	
95% CI [2]	-0.43, 0.96	-0.86, 0.11	-0.84, 0.18	-1.17, -0.38	
Difference (95% CI) in CFB [2]		-0.64 (-1.37, 0.10)		-0.45 (-1.04, 0.15)	
p-value [3]		0.087		0.140	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	18	35	40	76	
Mean (StdDev)	1.5 (1.20)	1.4 (1.22)	1.8 (1.35)	1.4 (1.37)	
Median	1.5	1.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C7D1 CFB					
n	17	33	40	74	
LS Mean (StdErr) [2]	-0.02 (0.306)	-0.25 (0.207)	-0.35 (0.259)	-0.86 (0.205)	
95% CI [2]	-0.63, 0.60	-0.67, 0.16	-0.86, 0.17	-1.27, -0.46	
Difference (95% CI) in CFB [2]		-0.24 (-0.88, 0.40)		-0.51 (-1.11, 0.08)	
Hedges'G (95% CI) in CFB		-0.19 (-0.80, 0.40)		-0.30 (-0.69, 0.09)	
p-value [3]		0.458		0.088	
					0.426

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	21	35	44	84	
Mean (StdDev)	2.1 (1.45)	2.3 (1.30)	2.7 (1.14)	2.8 (1.28)	
Median	2.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	21	35	44	84	
Mean (StdDev)	1.9 (1.28)	1.8 (1.26)	2.5 (1.17)	2.2 (1.32)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	20	34	43	82	
LS Mean (StdErr) [2]	-0.16 (0.319)	-0.43 (0.221)	-0.16 (0.186)	-0.57 (0.151)	
95% CI [2]	-0.81, 0.48	-0.88, 0.01	-0.53, 0.21	-0.86, -0.27	
Difference (95% CI) in CFB [2]		-0.27 (-0.94, 0.41)		-0.40 (-0.84, 0.03)	
p-value [3]		0.431		0.066	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	18	33	45	76	
Mean (StdDev)	2.1 (0.96)	1.5 (1.03)	2.4 (1.29)	2.0 (1.37)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C3D1 CFB					
n	17	33	44	76	
LS Mean (StdErr) [2]	0.13 (0.326)	-0.66 (0.216)	-0.29 (0.191)	-0.80 (0.158)	
95% CI [2]	-0.53, 0.79	-1.09, -0.23	-0.67, 0.09	-1.11, -0.48	
Difference (95% CI) in CFB [2]		-0.79 (-1.49, -0.10)		-0.51 (-0.95, -0.06)	
p-value [3]		0.027		0.027	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	17	33	39	80	
Mean (StdDev)	1.6 (1.22)	1.8 (1.34)	2.4 (1.31)	2.1 (1.34)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C4D1 CFB					
n	16	32	38	79	
LS Mean (StdErr) [2]	-0.28 (0.400)	-0.59 (0.275)	-0.28 (0.208)	-0.70 (0.160)	
95% CI [2]	-1.09, 0.52	-1.14, -0.03	-0.69, 0.14	-1.01, -0.38	
Difference (95% CI) in CFB [2]		-0.30 (-1.13, 0.52)		-0.42 (-0.89, 0.05)	
p-value [3]		0.462		0.081	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	32	40	77	
Mean (StdDev)	2.0 (1.25)	1.6 (1.04)	2.3 (1.22)	1.8 (1.33)	
Median	2.0	1.5	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	18	30	40	75	
LS Mean (StdErr) [2]	0.08 (0.389)	-0.70 (0.272)	-0.40 (0.200)	-0.98 (0.158)	
95% CI [2]	-0.70, 0.87	-1.25, -0.15	-0.80, -0.00	-1.29, -0.67	
Difference (95% CI) in CFB [2]		-0.79 (-1.62, 0.05)		-0.58 (-1.05, -0.12)	
p-value [3]		0.064		0.014	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	19	33	39	78	
Mean (StdDev)	2.1 (1.18)	1.6 (1.20)	2.6 (1.27)	1.8 (1.37)	
Median	2.0	1.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	18	31	39	76	
LS Mean (StdErr) [2]	-0.03 (0.375)	-0.73 (0.261)	-0.09 (0.208)	-0.84 (0.162)	
95% CI [2]	-0.78, 0.73	-1.25, -0.20	-0.50, 0.32	-1.17, -0.52	
Difference (95% CI) in CFB [2]		-0.70 (-1.50, 0.10)		-0.76 (-1.24, -0.27)	
p-value [3]		0.083		0.002	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	18	35	40	76	
Mean (StdDev)	1.8 (1.34)	1.4 (1.26)	2.4 (1.23)	1.9 (1.38)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	17	33	40	74	
LS Mean (StdErr) [2]	-0.11 (0.373)	-0.80 (0.253)	-0.26 (0.228)	-0.81 (0.180)	
95% CI [2]	-0.86, 0.64	-1.31, -0.29	-0.71, 0.19	-1.17, -0.45	
Difference (95% CI) in CFB [2]		-0.69 (-1.47, 0.09)		-0.55 (-1.07, -0.03)	
Hedges'G (95% CI) in CFB		-0.46 (-1.09, 0.13)		-0.36 (-0.76, 0.02)	
p-value [3]		0.083		0.039	
					0.875

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	21	35	44	84	
Mean (StdDev)	2.0 (1.48)	1.8 (1.04)	2.5 (1.30)	2.7 (1.02)	
Median	2.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	21	35	44	84	
Mean (StdDev)	1.8 (1.14)	1.3 (0.97)	2.2 (1.20)	2.0 (1.24)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C2D1 CFB					
n	20	34	43	82	
LS Mean (StdErr) [2]	0.08 (0.312)	-0.35 (0.216)	-0.21 (0.188)	-0.61 (0.152)	
95% CI [2]	-0.55, 0.71	-0.79, 0.08	-0.58, 0.16	-0.91, -0.31	
Difference (95% CI) in CFB [2]		-0.43 (-1.09, 0.23)		-0.40 (-0.84, 0.03)	
p-value [3]		0.194		0.071	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	18	33	45	76	
Mean (StdDev)	1.6 (1.10)	1.4 (1.03)	2.1 (1.47)	1.9 (1.12)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C3D1 CFB					
n	17	33	44	76	
LS Mean (StdErr) [2]	-0.03 (0.347)	-0.23 (0.230)	-0.33 (0.164)	-0.76 (0.136)	
95% CI [2]	-0.72, 0.67	-0.69, 0.24	-0.65, -0.00	-1.03, -0.49	
Difference (95% CI) in CFB [2]		-0.20 (-0.94, 0.54)		-0.43 (-0.81, -0.05)	
p-value [3]		0.589		0.028	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	17	33	39	80	
Mean (StdDev)	1.5 (1.18)	1.2 (0.87)	2.3 (1.34)	1.9 (1.29)	
Median	1.0	1.0	3.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C4D1 CFB					
n	16	32	38	79	
LS Mean (StdErr) [2]	-0.35 (0.359)	-0.45 (0.247)	-0.23 (0.219)	-0.78 (0.168)	
95% CI [2]	-1.07, 0.37	-0.95, 0.05	-0.66, 0.21	-1.11, -0.44	
Difference (95% CI) in CFB [2]		-0.10 (-0.84, 0.65)		-0.55 (-1.05, -0.06)	
p-value [3]		0.793		0.029	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	32	40	77	
Mean (StdDev)	1.7 (1.16)	1.3 (0.95)	2.2 (1.37)	1.8 (1.31)	
Median	2.0	1.0	3.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C5D1 CFB					
n	18	30	40	75	
LS Mean (StdErr) [2]	0.14 (0.366)	-0.54 (0.256)	-0.25 (0.210)	-0.95 (0.166)	
95% CI [2]	-0.59, 0.88	-1.05, -0.02	-0.67, 0.17	-1.28, -0.62	
Difference (95% CI) in CFB [2]		-0.68 (-1.47, 0.10)		-0.70 (-1.19, -0.21)	
p-value [3]		0.087		0.005	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	19	33	39	78	
Mean (StdDev)	1.8 (1.12)	1.2 (1.06)	2.4 (1.39)	1.7 (1.28)	
Median	2.0	1.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	18	31	39	76	
LS Mean (StdErr) [2]	0.41 (0.354)	-0.39 (0.246)	-0.02 (0.215)	-0.98 (0.168)	
95% CI [2]	-0.30, 1.12	-0.89, 0.10	-0.44, 0.41	-1.32, -0.65	
Difference (95% CI) in CFB [2]		-0.80 (-1.55, -0.05)		-0.97 (-1.47, -0.47)	
p-value [3]		0.037		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	18	35	40	76	
Mean (StdDev)	1.7 (1.28)	1.2 (1.05)	2.2 (1.33)	1.9 (1.33)	
Median	2.0	1.0	2.5	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	17	33	40	74	
LS Mean (StdErr) [2]	0.31 (0.376)	-0.41 (0.255)	-0.21 (0.207)	-0.85 (0.164)	
95% CI [2]	-0.45, 1.07	-0.92, 0.10	-0.62, 0.20	-1.18, -0.53	
Difference (95% CI) in CFB [2]		-0.72 (-1.51, 0.06)		-0.64 (-1.11, -0.17)	
Hedges'G (95% CI) in CFB		-0.48 (-1.11, 0.11)		-0.46 (-0.86, -0.08)	
p-value [3]		0.071		0.009	
					0.931

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	21	35	44	84	
Mean (StdDev)	1.8 (1.50)	1.6 (1.37)	1.7 (1.55)	2.0 (1.54)	
Median	2.0	1.0	1.5	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	21	35	44	84	
Mean (StdDev)	1.3 (1.32)	1.4 (1.24)	2.0 (1.57)	1.7 (1.54)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	20	34	43	82	
LS Mean (StdErr) [2]	-0.35 (0.244)	-0.16 (0.169)	0.20 (0.187)	-0.36 (0.151)	
95% CI [2]	-0.84, 0.14	-0.50, 0.18	-0.18, 0.57	-0.66, -0.06	
Difference (95% CI) in CFB [2]		0.19 (-0.33, 0.70)		-0.55 (-0.99, -0.12)	
p-value [3]		0.474		0.012	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	18	33	45	76	
Mean (StdDev)	1.2 (1.17)	1.2 (1.32)	1.6 (1.68)	1.4 (1.46)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C3D1 CFB					
n	17	33	44	76	
LS Mean (StdErr) [2]	-0.59 (0.293)	-0.27 (0.194)	-0.06 (0.182)	-0.52 (0.151)	
95% CI [2]	-1.17, 0.00	-0.66, 0.12	-0.42, 0.30	-0.82, -0.22	
Difference (95% CI) in CFB [2]		0.31 (-0.31, 0.94)		-0.46 (-0.88, -0.03)	
p-value [3]		0.316		0.036	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	17	33	39	80	
Mean (StdDev)	1.2 (1.20)	1.3 (1.36)	1.8 (1.39)	1.4 (1.42)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C4D1 CFB					
n	16	32	38	79	
LS Mean (StdErr) [2]	-0.47 (0.367)	-0.16 (0.252)	-0.06 (0.228)	-0.51 (0.176)	
95% CI [2]	-1.20, 0.27	-0.67, 0.35	-0.51, 0.40	-0.86, -0.16	
Difference (95% CI) in CFB [2]		0.30 (-0.45, 1.06)		-0.46 (-0.97, 0.06)	
p-value [3]		0.423		0.083	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	32	40	76	
Mean (StdDev)	1.1 (1.13)	1.4 (1.36)	1.6 (1.52)	1.3 (1.38)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C5D1 CFB					
n	18	30	40	74	
LS Mean (StdErr) [2]	-0.40 (0.355)	-0.23 (0.249)	-0.11 (0.229)	-0.62 (0.181)	
95% CI [2]	-1.12, 0.31	-0.73, 0.27	-0.57, 0.34	-0.98, -0.26	
Difference (95% CI) in CFB [2]		0.17 (-0.59, 0.93)		-0.51 (-1.04, 0.02)	
p-value [3]		0.655		0.061	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	19	33	39	78	
Mean (StdDev)	1.0 (1.11)	1.1 (1.27)	1.6 (1.48)	1.5 (1.51)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C6D1 CFB					
n	18	31	39	76	
LS Mean (StdErr) [2]	-0.54 (0.333)	-0.48 (0.232)	-0.08 (0.259)	-0.46 (0.202)	
95% CI [2]	-1.21, 0.13	-0.95, -0.02	-0.59, 0.43	-0.86, -0.06	
Difference (95% CI) in CFB [2]		0.06 (-0.65, 0.76)		-0.38 (-0.98, 0.22)	
p-value [3]		0.873		0.211	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	18	35	40	76	
Mean (StdDev)	1.2 (1.06)	1.3 (1.34)	1.6 (1.55)	1.4 (1.49)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C7D1 CFB					
n	17	33	40	74	
LS Mean (StdErr) [2]	-0.23 (0.313)	-0.18 (0.212)	0.04 (0.248)	-0.49 (0.197)	
95% CI [2]	-0.86, 0.40	-0.61, 0.24	-0.45, 0.54	-0.88, -0.10	
Difference (95% CI) in CFB [2]		0.04 (-0.61, 0.70)		-0.54 (-1.10, 0.03)	
Hedges'G (95% CI) in CFB		0.03 (-0.56, 0.64)		-0.32 (-0.72, 0.06)	
p-value [3]		0.894		0.063	
					0.181

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	21	35	44	84	
Mean (StdDev)	1.9 (1.39)	1.9 (1.21)	2.3 (1.27)	2.6 (1.12)	
Median	2.0	2.0	2.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	21	35	44	84	
Mean (StdDev)	1.7 (1.31)	1.6 (1.01)	1.8 (1.23)	2.0 (1.21)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	20	34	43	82	
LS Mean (StdErr) [2]	-0.32 (0.254)	-0.48 (0.176)	-0.42 (0.149)	-0.48 (0.120)	
95% CI [2]	-0.83, 0.19	-0.83, -0.12	-0.71, -0.12	-0.72, -0.24	
Difference (95% CI) in CFB [2]		-0.15 (-0.69, 0.39)		-0.06 (-0.41, 0.28)	
p-value [3]		0.572		0.715	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	18	33	45	76	
Mean (StdDev)	1.8 (1.22)	1.2 (1.08)	2.0 (1.33)	1.8 (1.32)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C3D1 CFB					
n	17	33	44	76	
LS Mean (StdErr) [2]	-0.18 (0.314)	-0.76 (0.208)	-0.25 (0.162)	-0.70 (0.134)	
95% CI [2]	-0.81, 0.45	-1.18, -0.34	-0.58, 0.07	-0.97, -0.43	
Difference (95% CI) in CFB [2]		-0.58 (-1.25, 0.09)		-0.44 (-0.82, -0.07)	
p-value [3]		0.087		0.022	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	17	33	39	80	
Mean (StdDev)	1.5 (1.28)	1.5 (1.00)	2.0 (1.08)	1.6 (1.26)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C4D1 CFB					
n	16	32	38	79	
LS Mean (StdErr) [2]	-0.34 (0.312)	-0.50 (0.215)	-0.33 (0.166)	-0.92 (0.128)	
95% CI [2]	-0.97, 0.29	-0.93, -0.07	-0.66, -0.00	-1.17, -0.66	
Difference (95% CI) in CFB [2]		-0.16 (-0.80, 0.49)		-0.59 (-0.96, -0.21)	
p-value [3]		0.624		0.003	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	32	40	77	
Mean (StdDev)	1.6 (1.22)	1.2 (0.92)	1.9 (1.22)	1.7 (1.32)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C5D1 CFB					
n	18	30	40	75	
LS Mean (StdErr) [2]	-0.49 (0.335)	-1.11 (0.234)	-0.39 (0.173)	-0.81 (0.136)	
95% CI [2]	-1.16, 0.19	-1.58, -0.63	-0.74, -0.05	-1.08, -0.55	
Difference (95% CI) in CFB [2]		-0.62 (-1.34, 0.10)		-0.42 (-0.82, -0.02)	
p-value [3]		0.089		0.039	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	19	33	39	78	
Mean (StdDev)	1.7 (1.10)	1.3 (1.29)	2.2 (1.25)	1.7 (1.36)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C6D1 CFB					
n	18	31	39	76	
LS Mean (StdErr) [2]	-0.22 (0.305)	-0.83 (0.212)	-0.02 (0.195)	-0.80 (0.152)	
95% CI [2]	-0.83, 0.39	-1.26, -0.41	-0.41, 0.37	-1.10, -0.50	
Difference (95% CI) in CFB [2]		-0.61 (-1.26, 0.03)		-0.78 (-1.23, -0.33)	
p-value [3]		0.063		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	18	35	40	76	
Mean (StdDev)	1.6 (1.38)	1.1 (1.14)	2.1 (1.36)	1.7 (1.40)	
Median	1.5	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	17	33	40	74	
LS Mean (StdErr) [2]	-0.16 (0.300)	-0.73 (0.203)	-0.13 (0.187)	-0.79 (0.148)	
95% CI [2]	-0.76, 0.45	-1.14, -0.32	-0.50, 0.24	-1.08, -0.50	
Difference (95% CI) in CFB [2]		-0.58 (-1.21, 0.05)		-0.66 (-1.09, -0.23)	
Hedges'G (95% CI) in CFB		-0.48 (-1.11, 0.11)		-0.53 (-0.93, -0.14)	
p-value [3]		0.070		0.003	
					0.804

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	21	35	44	84	
Mean (StdDev)	1.7 (1.56)	1.6 (1.21)	2.1 (1.31)	2.4 (1.28)	
Median	1.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	21	35	44	84	
Mean (StdDev)	1.3 (1.27)	1.2 (1.24)	1.5 (1.19)	1.8 (1.26)	
Median	1.0	1.0	1.0	2.0	
Min, Max	0, 4	0, 4	0, 3	0, 4	
C2D1 CFB					
n	20	34	43	82	
LS Mean (StdErr) [2]	-0.24 (0.264)	-0.38 (0.183)	-0.52 (0.174)	-0.56 (0.140)	
95% CI [2]	-0.77, 0.29	-0.75, -0.01	-0.86, -0.17	-0.84, -0.28	
Difference (95% CI) in CFB [2]		-0.14 (-0.70, 0.42)		-0.04 (-0.45, 0.36)	
p-value [3]		0.617		0.826	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	18	33	45	76	
Mean (StdDev)	1.3 (1.28)	1.1 (1.10)	1.7 (1.29)	1.6 (1.34)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C3D1 CFB					
n	17	33	44	76	
LS Mean (StdErr) [2]	-0.22 (0.292)	-0.48 (0.194)	-0.36 (0.173)	-0.74 (0.143)	
95% CI [2]	-0.81, 0.37	-0.87, -0.09	-0.70, -0.02	-1.03, -0.46	
Difference (95% CI) in CFB [2]		-0.26 (-0.88, 0.37)		-0.39 (-0.79, 0.02)	
p-value [3]		0.411		0.061	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	17	33	39	80	
Mean (StdDev)	1.4 (1.37)	1.0 (0.95)	1.7 (1.06)	1.5 (1.34)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C4D1 CFB					
n	16	32	38	79	
LS Mean (StdErr) [2]	-0.29 (0.286)	-0.70 (0.197)	-0.55 (0.187)	-0.83 (0.143)	
95% CI [2]	-0.87, 0.29	-1.10, -0.31	-0.92, -0.18	-1.11, -0.54	
Difference (95% CI) in CFB [2]		-0.41 (-1.01, 0.18)		-0.28 (-0.70, 0.15)	
p-value [3]		0.165		0.197	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	32	40	77	
Mean (StdDev)	1.3 (1.38)	1.1 (1.01)	1.7 (1.27)	1.5 (1.29)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C5D1 CFB					
n	18	30	40	75	
LS Mean (StdErr) [2]	-0.03 (0.335)	-0.65 (0.234)	-0.53 (0.186)	-0.90 (0.146)	
95% CI [2]	-0.70, 0.64	-1.12, -0.18	-0.90, -0.16	-1.19, -0.61	
Difference (95% CI) in CFB [2]		-0.62 (-1.34, 0.09)		-0.37 (-0.80, 0.06)	
p-value [3]		0.086		0.091	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	19	33	39	78	
Mean (StdDev)	1.4 (1.26)	1.0 (1.09)	1.8 (1.25)	1.6 (1.42)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C6D1 CFB					
n	18	31	39	76	
LS Mean (StdErr) [2]	-0.11 (0.293)	-0.68 (0.204)	-0.30 (0.203)	-0.88 (0.158)	
95% CI [2]	-0.70, 0.48	-1.09, -0.27	-0.70, 0.10	-1.19, -0.56	
Difference (95% CI) in CFB [2]		-0.57 (-1.19, 0.05)		-0.58 (-1.05, -0.11)	
p-value [3]		0.072		0.016	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	18	35	40	76	
Mean (StdDev)	1.2 (1.25)	1.0 (1.16)	1.7 (1.34)	1.4 (1.43)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	17	33	40	74	
LS Mean (StdErr) [2]	-0.15 (0.305)	-0.59 (0.207)	-0.23 (0.199)	-0.79 (0.158)	
95% CI [2]	-0.77, 0.46	-1.00, -0.17	-0.63, 0.16	-1.11, -0.48	
Difference (95% CI) in CFB [2]		-0.44 (-1.07, 0.20)		-0.56 (-1.01, -0.10)	
Hedges'G (95% CI) in CFB		-0.35 (-0.98, 0.23)		-0.42 (-0.82, -0.04)	
p-value [3]		0.176		0.016	
					0.796

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	21	35	44	84	
Mean (StdDev)	2.8 (0.87)	2.5 (1.09)	3.1 (0.94)	3.1 (0.93)	
Median	3.0	2.0	3.0	3.0	
Min, Max	1, 4	0, 4	0, 4	1, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	21	35	44	84	
Mean (StdDev)	2.4 (1.07)	2.1 (0.90)	2.6 (1.09)	2.7 (1.02)	
Median	2.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	20	34	43	82	
LS Mean (StdErr) [2]	-0.72 (0.247)	-0.58 (0.171)	-0.48 (0.150)	-0.41 (0.121)	
95% CI [2]	-1.22, -0.23	-0.93, -0.24	-0.78, -0.19	-0.65, -0.17	
Difference (95% CI) in CFB [2]		0.14 (-0.38, 0.66)		0.07 (-0.28, 0.42)	
p-value [3]		0.597		0.694	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	18	33	45	76	
Mean (StdDev)	2.6 (0.78)	1.9 (1.02)	2.6 (1.16)	2.4 (1.15)	
Median	3.0	2.0	3.0	3.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	17	33	44	76	
LS Mean (StdErr) [2]	-0.08 (0.255)	-0.56 (0.169)	-0.45 (0.160)	-0.64 (0.133)	
95% CI [2]	-0.59, 0.43	-0.90, -0.22	-0.77, -0.14	-0.90, -0.38	
Difference (95% CI) in CFB [2]		-0.48 (-1.02, 0.07)		-0.19 (-0.56, 0.19)	
p-value [3]		0.084		0.327	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	17	33	39	80	
Mean (StdDev)	2.2 (1.19)	2.0 (1.05)	2.5 (1.23)	2.5 (1.25)	
Median	2.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	16	32	38	79	
LS Mean (StdErr) [2]	-0.80 (0.304)	-0.53 (0.209)	-0.55 (0.180)	-0.53 (0.138)	
95% CI [2]	-1.41, -0.19	-0.95, -0.11	-0.91, -0.19	-0.81, -0.26	
Difference (95% CI) in CFB [2]		0.27 (-0.36, 0.90)		0.02 (-0.39, 0.43)	
p-value [3]		0.394		0.927	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	32	41	77	
Mean (StdDev)	2.2 (1.03)	1.8 (1.14)	2.7 (1.00)	2.2 (1.32)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C5D1 CFB					
n	18	30	41	75	
LS Mean (StdErr) [2]	-0.69 (0.332)	-0.94 (0.232)	-0.35 (0.186)	-0.89 (0.148)	
95% CI [2]	-1.36, -0.02	-1.41, -0.47	-0.72, 0.02	-1.19, -0.60	
Difference (95% CI) in CFB [2]		-0.25 (-0.96, 0.46)		-0.54 (-0.97, -0.11)	
p-value [3]		0.479		0.015	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	19	33	39	78	
Mean (StdDev)	2.4 (0.84)	1.9 (1.06)	2.6 (1.35)	2.3 (1.30)	
Median	2.0	2.0	3.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	18	31	39	76	
LS Mean (StdErr) [2]	-0.24 (0.260)	-0.59 (0.181)	-0.31 (0.214)	-0.68 (0.166)	
95% CI [2]	-0.76, 0.29	-0.96, -0.23	-0.73, 0.12	-1.01, -0.35	
Difference (95% CI) in CFB [2]		-0.36 (-0.91, 0.20)		-0.37 (-0.86, 0.12)	
p-value [3]		0.200		0.142	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	18	35	40	76	
Mean (StdDev)	2.4 (0.92)	1.8 (0.91)	2.6 (1.20)	2.3 (1.28)	
Median	2.5	2.0	3.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	17	33	40	74	
LS Mean (StdErr) [2]	-0.08 (0.291)	-0.63 (0.197)	-0.43 (0.187)	-0.69 (0.148)	
95% CI [2]	-0.67, 0.50	-1.03, -0.24	-0.80, -0.06	-0.98, -0.40	
Difference (95% CI) in CFB [2]		-0.55 (-1.16, 0.06)		-0.26 (-0.69, 0.16)	
Hedges'G (95% CI) in CFB		-0.47 (-1.10, 0.12)		-0.21 (-0.61, 0.17)	
p-value [3]		0.075		0.223	
					0.498

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	21	35	44	84	
Mean (StdDev)	2.3 (1.62)	2.4 (1.09)	2.5 (1.39)	2.5 (1.28)	
Median	2.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	21	35	44	84	
Mean (StdDev)	1.8 (1.40)	1.8 (1.26)	2.4 (1.10)	2.1 (1.40)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	20	34	43	82	
LS Mean (StdErr) [2]	-0.54 (0.301)	-0.66 (0.208)	-0.13 (0.172)	-0.36 (0.139)	
95% CI [2]	-1.14, 0.07	-1.08, -0.24	-0.47, 0.21	-0.63, -0.08	
Difference (95% CI) in CFB [2]		-0.12 (-0.76, 0.52)		-0.23 (-0.63, 0.17)	
p-value [3]		0.701		0.254	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	18	33	45	76	
Mean (StdDev)	2.1 (1.26)	1.5 (1.12)	2.4 (1.19)	1.9 (1.34)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	17	33	44	76	
LS Mean (StdErr) [2]	-0.40 (0.333)	-0.97 (0.221)	-0.10 (0.186)	-0.48 (0.154)	
95% CI [2]	-1.07, 0.27	-1.41, -0.52	-0.47, 0.27	-0.78, -0.17	
Difference (95% CI) in CFB [2]		-0.56 (-1.27, 0.15)		-0.38 (-0.82, 0.06)	
p-value [3]		0.118		0.087	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	17	33	39	80	
Mean (StdDev)	1.4 (1.37)	1.4 (1.30)	2.3 (1.18)	2.0 (1.42)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	16	32	38	79	
LS Mean (StdErr) [2]	-0.68 (0.356)	-0.81 (0.245)	-0.11 (0.181)	-0.42 (0.139)	
95% CI [2]	-1.40, 0.03	-1.30, -0.31	-0.47, 0.25	-0.70, -0.15	
Difference (95% CI) in CFB [2]		-0.12 (-0.86, 0.61)		-0.31 (-0.72, 0.10)	
p-value [3]		0.740		0.137	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	32	41	77	
Mean (StdDev)	1.7 (1.60)	1.6 (1.36)	2.1 (1.40)	1.8 (1.50)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	18	30	41	75	
LS Mean (StdErr) [2]	-0.38 (0.338)	-0.73 (0.236)	-0.39 (0.187)	-0.72 (0.148)	
95% CI [2]	-1.06, 0.30	-1.21, -0.26	-0.76, -0.02	-1.01, -0.43	
Difference (95% CI) in CFB [2]		-0.36 (-1.08, 0.36)		-0.33 (-0.76, 0.10)	
p-value [3]		0.323		0.135	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	19	33	39	78	
Mean (StdDev)	1.9 (1.45)	1.3 (1.19)	2.4 (1.21)	1.8 (1.45)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	18	31	39	76	
LS Mean (StdErr) [2]	-0.17 (0.305)	-1.04 (0.212)	-0.06 (0.203)	-0.65 (0.158)	
95% CI [2]	-0.79, 0.44	-1.47, -0.61	-0.46, 0.34	-0.96, -0.34	
Difference (95% CI) in CFB [2]		-0.86 (-1.51, -0.22)		-0.59 (-1.06, -0.12)	
p-value [3]		0.010		0.014	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	18	35	40	76	
Mean (StdDev)	1.8 (1.66)	1.4 (1.35)	2.2 (1.32)	1.6 (1.45)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	17	33	40	74	
LS Mean (StdErr) [2]	-0.29 (0.302)	-0.87 (0.205)	-0.31 (0.213)	-0.74 (0.169)	
95% CI [2]	-0.90, 0.32	-1.28, -0.46	-0.73, 0.11	-1.08, -0.41	
Difference (95% CI) in CFB [2]		-0.58 (-1.21, 0.05)		-0.43 (-0.92, 0.06)	
Hedges'G (95% CI) in CFB		-0.47 (-1.10, 0.11)		-0.30 (-0.70, 0.08)	
p-value [3]		0.072		0.082	
					0.718

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	21	35	44	84	
Mean (StdDev)	2.6 (1.29)	2.7 (0.98)	2.9 (1.06)	3.1 (0.94)	
Median	3.0	3.0	3.0	3.0	
Min, Max	0, 4	1, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	21	35	44	84	
Mean (StdDev)	2.2 (1.21)	1.8 (1.27)	2.3 (1.10)	2.5 (1.18)	
Median	2.0	2.0	2.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	20	34	43	82	
LS Mean (StdErr) [2]	-0.39 (0.301)	-0.90 (0.208)	-0.66 (0.154)	-0.63 (0.124)	
95% CI [2]	-1.00, 0.21	-1.32, -0.49	-0.97, -0.36	-0.88, -0.38	
Difference (95% CI) in CFB [2]		-0.51 (-1.15, 0.12)		0.03 (-0.32, 0.39)	
p-value [3]		0.113		0.859	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	18	33	45	76	
Mean (StdDev)	2.4 (1.14)	1.8 (1.12)	2.4 (1.25)	2.2 (1.24)	
Median	2.5	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	17	33	44	76	
LS Mean (StdErr) [2]	-0.39 (0.350)	-1.02 (0.232)	-0.42 (0.166)	-0.88 (0.137)	
95% CI [2]	-1.09, 0.31	-1.49, -0.55	-0.75, -0.10	-1.15, -0.61	
Difference (95% CI) in CFB [2]		-0.63 (-1.37, 0.12)		-0.46 (-0.85, -0.07)	
p-value [3]		0.097		0.021	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	17	33	39	80	
Mean (StdDev)	2.4 (1.27)	1.8 (1.06)	2.5 (1.14)	2.2 (1.30)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	16	32	38	79	
LS Mean (StdErr) [2]	-0.30 (0.322)	-0.92 (0.221)	-0.40 (0.183)	-0.97 (0.141)	
95% CI [2]	-0.94, 0.35	-1.36, -0.47	-0.76, -0.03	-1.25, -0.69	
Difference (95% CI) in CFB [2]		-0.62 (-1.29, 0.04)		-0.57 (-0.99, -0.16)	
p-value [3]		0.067		0.007	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	32	41	76	
Mean (StdDev)	2.3 (1.33)	1.8 (1.01)	2.3 (1.13)	2.1 (1.27)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	18	30	41	74	
LS Mean (StdErr) [2]	-0.06 (0.341)	-1.01 (0.239)	-0.63 (0.170)	-1.04 (0.135)	
95% CI [2]	-0.74, 0.63	-1.49, -0.53	-0.97, -0.30	-1.30, -0.77	
Difference (95% CI) in CFB [2]		-0.95 (-1.68, -0.22)		-0.41 (-0.80, -0.01)	
p-value [3]		0.012		0.043	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	19	33	39	78	
Mean (StdDev)	2.6 (1.12)	1.7 (1.05)	2.4 (1.18)	2.0 (1.41)	
Median	3.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	18	31	39	76	
LS Mean (StdErr) [2]	0.09 (0.302)	-1.17 (0.210)	-0.57 (0.193)	-1.15 (0.150)	
95% CI [2]	-0.51, 0.70	-1.59, -0.75	-0.95, -0.19	-1.44, -0.85	
Difference (95% CI) in CFB [2]		-1.26 (-1.90, -0.62)		-0.58 (-1.02, -0.13)	
p-value [3]		<0.001		0.012	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	18	35	40	76	
Mean (StdDev)	2.2 (1.44)	1.7 (1.20)	2.3 (1.30)	2.0 (1.39)	
Median	2.5	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	17	33	40	74	
LS Mean (StdErr) [2]	-0.23 (0.322)	-0.93 (0.218)	-0.49 (0.190)	-1.01 (0.151)	
95% CI [2]	-0.88, 0.42	-1.37, -0.49	-0.87, -0.12	-1.31, -0.71	
Difference (95% CI) in CFB [2]		-0.70 (-1.38, -0.03)		-0.51 (-0.95, -0.08)	
Hedges'G (95% CI) in CFB		-0.54 (-1.18, 0.04)		-0.40 (-0.80, -0.02)	
p-value [3]		0.042		0.021	
					0.601

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	21	35	44	84	
Mean (StdDev)	2.8 (1.14)	2.9 (0.85)	3.2 (0.77)	3.3 (0.96)	
Median	3.0	3.0	3.0	3.5	
Min, Max	0, 4	1, 4	2, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	21	35	44	84	
Mean (StdDev)	2.3 (1.06)	2.1 (1.05)	2.8 (0.94)	2.4 (1.08)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C2D1 CFB					
n	20	34	43	82	
LS Mean (StdErr) [2]	-0.32 (0.235)	-0.72 (0.163)	-0.50 (0.151)	-0.82 (0.122)	
95% CI [2]	-0.80, 0.15	-1.05, -0.40	-0.79, -0.20	-1.06, -0.58	
Difference (95% CI) in CFB [2]		-0.40 (-0.90, 0.10)		-0.33 (-0.67, 0.02)	
p-value [3]		0.112		0.067	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	18	33	45	76	
Mean (StdDev)	2.4 (1.04)	1.8 (1.22)	2.5 (1.12)	2.3 (1.13)	
Median	2.5	2.0	3.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	17	33	44	76	
LS Mean (StdErr) [2]	-0.23 (0.318)	-1.03 (0.211)	-0.68 (0.161)	-0.99 (0.133)	
95% CI [2]	-0.86, 0.41	-1.45, -0.60	-1.00, -0.36	-1.25, -0.72	
Difference (95% CI) in CFB [2]		-0.80 (-1.48, -0.12)		-0.30 (-0.68, 0.07)	
p-value [3]		0.022		0.113	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	17	33	39	80	
Mean (StdDev)	2.2 (1.33)	1.6 (1.08)	2.6 (1.05)	2.3 (1.11)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	16	32	38	79	
LS Mean (StdErr) [2]	-0.58 (0.321)	-1.26 (0.220)	-0.63 (0.166)	-0.98 (0.127)	
95% CI [2]	-1.23, 0.06	-1.70, -0.81	-0.96, -0.30	-1.23, -0.72	
Difference (95% CI) in CFB [2]		-0.67 (-1.33, -0.01)		-0.34 (-0.72, 0.03)	
p-value [3]		0.048		0.071	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	32	41	77	
Mean (StdDev)	2.4 (1.30)	1.9 (1.06)	2.4 (1.29)	2.3 (1.23)	
Median	3.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	18	30	41	75	
LS Mean (StdErr) [2]	-0.14 (0.349)	-0.96 (0.244)	-0.75 (0.180)	-1.05 (0.143)	
95% CI [2]	-0.85, 0.56	-1.45, -0.47	-1.11, -0.40	-1.33, -0.77	
Difference (95% CI) in CFB [2]		-0.82 (-1.56, -0.07)		-0.30 (-0.71, 0.12)	
p-value [3]		0.033		0.162	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	19	33	39	78	
Mean (StdDev)	2.6 (1.12)	1.7 (1.01)	2.6 (1.19)	2.1 (1.36)	
Median	3.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	18	31	39	76	
LS Mean (StdErr) [2]	-0.15 (0.308)	-1.18 (0.215)	-0.62 (0.201)	-1.13 (0.157)	
95% CI [2]	-0.77, 0.47	-1.61, -0.75	-1.02, -0.22	-1.44, -0.82	
Difference (95% CI) in CFB [2]		-1.03 (-1.69, -0.38)		-0.51 (-0.98, -0.05)	
p-value [3]		0.003		0.031	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	18	35	40	76	
Mean (StdDev)	2.3 (1.46)	1.8 (1.09)	2.4 (1.28)	2.1 (1.35)	
Median	2.5	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	17	33	40	74	
LS Mean (StdErr) [2]	-0.16 (0.319)	-0.98 (0.216)	-0.69 (0.201)	-1.15 (0.159)	
95% CI [2]	-0.80, 0.48	-1.41, -0.54	-1.09, -0.29	-1.47, -0.84	
Difference (95% CI) in CFB [2]		-0.82 (-1.49, -0.15)		-0.46 (-0.92, -0.00)	
Hedges'G (95% CI) in CFB		-0.64 (-1.28, -0.05)		-0.34 (-0.74, 0.04)	
p-value [3]		0.017		0.049	
					0.429

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	21	35	44	84	
Mean (StdDev)	2.1 (1.49)	1.0 (1.21)	2.4 (1.43)	2.3 (1.44)	
Median	2.0	0.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	21	35	44	84	
Mean (StdDev)	1.8 (1.44)	0.9 (1.08)	2.0 (1.43)	1.7 (1.49)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C2D1 CFB					
n	20	34	43	82	
LS Mean (StdErr) [2]	-0.06 (0.292)	0.04 (0.202)	-0.14 (0.195)	-0.33 (0.157)	
95% CI [2]	-0.64, 0.53	-0.37, 0.44	-0.53, 0.24	-0.64, -0.02	
Difference (95% CI) in CFB [2]		0.10 (-0.52, 0.71)		-0.19 (-0.64, 0.26)	
p-value [3]		0.758		0.414	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	18	33	45	76	
Mean (StdDev)	1.9 (1.30)	0.8 (1.06)	2.0 (1.43)	1.6 (1.50)	
Median	2.0	0.0	2.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C3D1 CFB					
n	17	33	44	76	
LS Mean (StdErr) [2]	-0.04 (0.359)	-0.05 (0.238)	-0.23 (0.206)	-0.59 (0.171)	
95% CI [2]	-0.76, 0.68	-0.53, 0.43	-0.64, 0.18	-0.93, -0.25	
Difference (95% CI) in CFB [2]		-0.01 (-0.77, 0.76)		-0.36 (-0.84, 0.12)	
p-value [3]		0.980		0.140	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	17	33	39	80	
Mean (StdDev)	1.6 (1.22)	0.9 (1.19)	2.0 (1.31)	1.8 (1.44)	
Median	1.0	0.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	16	32	38	79	
LS Mean (StdErr) [2]	-0.35 (0.339)	0.00 (0.233)	-0.29 (0.205)	-0.43 (0.157)	
95% CI [2]	-1.04, 0.33	-0.47, 0.47	-0.69, 0.12	-0.74, -0.12	
Difference (95% CI) in CFB [2]		0.35 (-0.35, 1.06)		-0.14 (-0.61, 0.32)	
p-value [3]		0.316		0.543	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	32	41	77	
Mean (StdDev)	1.5 (1.31)	0.8 (1.12)	2.0 (1.37)	1.7 (1.44)	
Median	1.0	0.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	18	30	41	75	
LS Mean (StdErr) [2]	-0.28 (0.315)	-0.06 (0.220)	-0.25 (0.230)	-0.50 (0.183)	
95% CI [2]	-0.92, 0.35	-0.50, 0.39	-0.71, 0.20	-0.86, -0.14	
Difference (95% CI) in CFB [2]		0.23 (-0.45, 0.90)		-0.25 (-0.78, 0.29)	
p-value [3]		0.501		0.359	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	19	33	39	78	
Mean (StdDev)	1.8 (1.34)	0.8 (1.18)	1.9 (1.52)	1.6 (1.37)	
Median	2.0	0.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	18	31	39	76	
LS Mean (StdErr) [2]	-0.18 (0.330)	-0.11 (0.230)	-0.43 (0.241)	-0.67 (0.187)	
95% CI [2]	-0.84, 0.49	-0.57, 0.36	-0.90, 0.05	-1.04, -0.30	
Difference (95% CI) in CFB [2]		0.07 (-0.63, 0.77)		-0.24 (-0.80, 0.31)	
p-value [3]		0.841		0.390	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	18	35	40	76	
Mean (StdDev)	1.9 (1.43)	0.9 (1.16)	2.0 (1.54)	1.4 (1.41)	
Median	2.0	0.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	17	33	40	74	
LS Mean (StdErr) [2]	0.04 (0.324)	-0.03 (0.220)	-0.16 (0.240)	-0.60 (0.190)	
95% CI [2]	-0.62, 0.69	-0.47, 0.42	-0.63, 0.32	-0.98, -0.22	
Difference (95% CI) in CFB [2]		-0.06 (-0.74, 0.62)		-0.45 (-0.99, 0.10)	
Hedges'G (95% CI) in CFB		-0.05 (-0.65, 0.55)		-0.28 (-0.67, 0.11)	
p-value [3]		0.851		0.110	
					0.444

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	21	35	44	84	
Mean (StdDev)	1.1 (1.00)	1.4 (1.06)	2.0 (1.24)	1.9 (1.39)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	21	35	44	84	
Mean (StdDev)	1.0 (1.07)	1.1 (0.87)	1.7 (1.04)	1.5 (1.38)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 3	0, 3	0, 4	
C2D1 CFB					
n	20	34	43	82	
LS Mean (StdErr) [2]	-0.29 (0.237)	-0.40 (0.164)	-0.39 (0.139)	-0.51 (0.112)	
95% CI [2]	-0.77, 0.18	-0.72, -0.07	-0.66, -0.11	-0.74, -0.29	
Difference (95% CI) in CFB [2]		-0.10 (-0.60, 0.40)		-0.13 (-0.45, 0.19)	
p-value [3]		0.686		0.438	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	18	33	45	76	
Mean (StdDev)	1.3 (1.13)	0.8 (0.76)	1.7 (1.17)	1.3 (1.35)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 2	0, 4	0, 4	
C3D1 CFB					
n	17	33	44	76	
LS Mean (StdErr) [2]	0.10 (0.336)	-0.62 (0.222)	-0.48 (0.175)	-0.78 (0.145)	
95% CI [2]	-0.58, 0.77	-1.06, -0.17	-0.83, -0.14	-1.06, -0.49	
Difference (95% CI) in CFB [2]		-0.71 (-1.43, 0.00)		-0.29 (-0.70, 0.12)	
p-value [3]		0.051		0.160	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	17	33	39	80	
Mean (StdDev)	1.4 (1.22)	0.6 (0.82)	1.7 (1.13)	1.3 (1.27)	
Median	1.0	0.0	2.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C4D1 CFB					
n	16	32	38	79	
LS Mean (StdErr) [2]	0.22 (0.292)	-0.78 (0.201)	-0.47 (0.201)	-0.74 (0.154)	
95% CI [2]	-0.36, 0.81	-1.18, -0.37	-0.87, -0.08	-1.05, -0.43	
Difference (95% CI) in CFB [2]		-1.00 (-1.61, -0.39)		-0.27 (-0.72, 0.19)	
p-value [3]		0.002		0.250	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	32	41	77	
Mean (StdDev)	1.2 (1.17)	0.6 (0.76)	1.7 (1.11)	1.3 (1.31)	
Median	1.0	0.0	1.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C5D1 CFB					
n	18	30	41	75	
LS Mean (StdErr) [2]	0.06 (0.276)	-0.82 (0.193)	-0.54 (0.183)	-0.82 (0.145)	
95% CI [2]	-0.49, 0.62	-1.21, -0.44	-0.91, -0.18	-1.11, -0.54	
Difference (95% CI) in CFB [2]		-0.89 (-1.48, -0.30)		-0.28 (-0.70, 0.14)	
p-value [3]		0.004		0.192	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	19	33	39	78	
Mean (StdDev)	1.3 (1.06)	0.7 (0.85)	1.7 (1.22)	1.3 (1.27)	
Median	1.0	0.0	2.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C6D1 CFB					
n	18	31	39	76	
LS Mean (StdErr) [2]	0.23 (0.296)	-0.67 (0.206)	-0.53 (0.180)	-0.79 (0.140)	
95% CI [2]	-0.36, 0.83	-1.09, -0.26	-0.89, -0.17	-1.06, -0.51	
Difference (95% CI) in CFB [2]		-0.91 (-1.53, -0.28)		-0.25 (-0.67, 0.16)	
p-value [3]		0.006		0.231	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	18	35	40	76	
Mean (StdDev)	1.1 (1.00)	0.7 (0.89)	1.5 (1.15)	1.1 (1.26)	
Median	1.0	0.0	1.0	1.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C7D1 CFB					
n	17	33	40	74	
LS Mean (StdErr) [2]	0.23 (0.251)	-0.44 (0.170)	-0.64 (0.183)	-0.81 (0.145)	
95% CI [2]	-0.28, 0.73	-0.79, -0.10	-1.00, -0.28	-1.10, -0.53	
Difference (95% CI) in CFB [2]		-0.67 (-1.20, -0.14)		-0.17 (-0.59, 0.25)	
Hedges'G (95% CI) in CFB		-0.66 (-1.31, -0.08)		-0.14 (-0.53, 0.24)	
p-value [3]		0.014		0.413	
					0.308

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	21	35	44	84	
Mean (StdDev)	0.9 (1.14)	0.8 (1.08)	1.4 (1.32)	1.8 (1.53)	
Median	1.0	0.0	1.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	21	35	44	84	
Mean (StdDev)	1.0 (1.34)	0.9 (1.17)	1.3 (1.34)	1.4 (1.42)	
Median	0.0	0.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	20	34	43	82	
LS Mean (StdErr) [2]	-0.06 (0.255)	0.03 (0.176)	-0.05 (0.167)	-0.26 (0.135)	
95% CI [2]	-0.57, 0.45	-0.32, 0.39	-0.38, 0.28	-0.52, 0.01	
Difference (95% CI) in CFB [2]		0.09 (-0.45, 0.63)		-0.21 (-0.59, 0.18)	
p-value [3]		0.738		0.292	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	18	33	45	76	
Mean (StdDev)	0.7 (0.91)	0.8 (1.06)	1.2 (1.27)	1.1 (1.31)	
Median	0.0	0.0	1.0	1.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C3D1 CFB					
n	17	33	44	76	
LS Mean (StdErr) [2]	-0.16 (0.258)	0.04 (0.171)	-0.20 (0.192)	-0.62 (0.159)	
95% CI [2]	-0.68, 0.36	-0.31, 0.38	-0.58, 0.18	-0.94, -0.31	
Difference (95% CI) in CFB [2]		0.20 (-0.35, 0.75)		-0.42 (-0.87, 0.02)	
p-value [3]		0.468		0.063	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	17	33	39	80	
Mean (StdDev)	1.2 (1.09)	0.5 (0.80)	1.4 (1.35)	1.3 (1.33)	
Median	1.0	0.0	1.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C4D1 CFB					
n	16	32	38	79	
LS Mean (StdErr) [2]	0.17 (0.306)	-0.41 (0.210)	-0.17 (0.205)	-0.58 (0.157)	
95% CI [2]	-0.45, 0.78	-0.83, 0.02	-0.58, 0.23	-0.89, -0.27	
Difference (95% CI) in CFB [2]		-0.57 (-1.21, 0.06)		-0.41 (-0.87, 0.06)	
p-value [3]		0.075		0.085	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	32	41	77	
Mean (StdDev)	0.8 (1.07)	0.3 (0.55)	1.4 (1.30)	1.2 (1.35)	
Median	1.0	0.0	1.0	1.0	
Min, Max	0, 4	0, 2	0, 4	0, 4	
C5D1 CFB					
n	18	30	41	75	
LS Mean (StdErr) [2]	0.05 (0.239)	-0.50 (0.167)	-0.13 (0.192)	-0.59 (0.152)	
95% CI [2]	-0.43, 0.53	-0.84, -0.17	-0.51, 0.25	-0.89, -0.29	
Difference (95% CI) in CFB [2]		-0.55 (-1.07, -0.04)		-0.47 (-0.91, -0.02)	
p-value [3]		0.035		0.040	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	19	33	39	78	
Mean (StdDev)	0.9 (1.03)	0.4 (0.75)	1.4 (1.33)	1.2 (1.29)	
Median	1.0	0.0	1.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C6D1 CFB					
n	18	31	39	76	
LS Mean (StdErr) [2]	0.03 (0.239)	-0.46 (0.166)	-0.20 (0.204)	-0.66 (0.159)	
95% CI [2]	-0.45, 0.51	-0.79, -0.13	-0.60, 0.21	-0.97, -0.34	
Difference (95% CI) in CFB [2]		-0.49 (-1.00, 0.02)		-0.46 (-0.94, 0.01)	
p-value [3]		0.057		0.054	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	18	35	40	76	
Mean (StdDev)	0.8 (0.99)	0.5 (0.82)	1.3 (1.26)	1.1 (1.37)	
Median	0.5	0.0	1.0	0.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C7D1 CFB					
n	17	33	40	74	
LS Mean (StdErr) [2]	0.16 (0.251)	-0.15 (0.170)	-0.15 (0.197)	-0.63 (0.156)	
95% CI [2]	-0.34, 0.67	-0.49, 0.19	-0.54, 0.24	-0.94, -0.32	
Difference (95% CI) in CFB [2]		-0.31 (-0.84, 0.21)		-0.47 (-0.92, -0.02)	
Hedges'G (95% CI) in CFB		-0.31 (-0.93, 0.28)		-0.36 (-0.76, 0.03)	
p-value [3]		0.235		0.040	
					0.622

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	21	35	44	84	
Mean (StdDev)	1.6 (1.07)	1.5 (1.17)	2.2 (1.11)	2.2 (1.28)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	21	35	44	84	
Mean (StdDev)	1.2 (1.03)	1.0 (1.04)	1.7 (1.33)	1.6 (1.30)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C2D1 CFB					
n	20	34	43	82	
LS Mean (StdErr) [2]	-0.48 (0.264)	-0.57 (0.183)	-0.54 (0.176)	-0.63 (0.142)	
95% CI [2]	-1.01, 0.05	-0.93, -0.20	-0.89, -0.19	-0.91, -0.34	
Difference (95% CI) in CFB [2]		-0.09 (-0.65, 0.47)		-0.09 (-0.49, 0.32)	
p-value [3]		0.751		0.670	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	18	33	45	76	
Mean (StdDev)	1.4 (1.04)	1.0 (1.06)	1.6 (1.15)	1.5 (1.14)	
Median	1.5	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	17	33	44	76	
LS Mean (StdErr) [2]	-0.34 (0.299)	-0.54 (0.198)	-0.56 (0.161)	-0.74 (0.133)	
95% CI [2]	-0.94, 0.26	-0.94, -0.14	-0.88, -0.24	-1.01, -0.48	
Difference (95% CI) in CFB [2]		-0.20 (-0.84, 0.44)		-0.18 (-0.56, 0.20)	
p-value [3]		0.531		0.344	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	17	33	39	80	
Mean (StdDev)	1.4 (1.23)	0.9 (1.04)	1.6 (1.27)	1.6 (1.24)	
Median	1.0	1.0	1.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	16	32	38	79	
LS Mean (StdErr) [2]	-0.27 (0.320)	-0.78 (0.220)	-0.45 (0.200)	-0.67 (0.154)	
95% CI [2]	-0.91, 0.38	-1.22, -0.33	-0.85, -0.06	-0.97, -0.36	
Difference (95% CI) in CFB [2]		-0.51 (-1.18, 0.15)		-0.21 (-0.67, 0.24)	
p-value [3]		0.127		0.353	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	32	41	77	
Mean (StdDev)	1.0 (1.11)	0.8 (0.88)	1.7 (1.35)	1.3 (1.28)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C5D1 CFB					
n	18	30	41	75	
LS Mean (StdErr) [2]	-0.46 (0.278)	-0.67 (0.194)	-0.43 (0.193)	-0.92 (0.153)	
95% CI [2]	-1.02, 0.10	-1.07, -0.28	-0.81, -0.04	-1.22, -0.61	
Difference (95% CI) in CFB [2]		-0.22 (-0.81, 0.38)		-0.49 (-0.94, -0.04)	
p-value [3]		0.470		0.031	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	19	33	39	78	
Mean (StdDev)	1.3 (1.05)	0.6 (0.87)	1.7 (1.37)	1.2 (1.17)	
Median	1.0	0.0	2.0	1.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C6D1 CFB					
n	18	31	39	76	
LS Mean (StdErr) [2]	-0.29 (0.290)	-1.00 (0.202)	-0.40 (0.205)	-1.15 (0.159)	
95% CI [2]	-0.87, 0.29	-1.41, -0.60	-0.80, 0.01	-1.46, -0.83	
Difference (95% CI) in CFB [2]		-0.72 (-1.33, -0.10)		-0.75 (-1.22, -0.28)	
p-value [3]		0.024		0.002	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	18	35	40	76	
Mean (StdDev)	1.1 (1.18)	0.9 (1.05)	1.8 (1.38)	1.3 (1.31)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C7D1 CFB					
n	17	33	40	74	
LS Mean (StdErr) [2]	-0.26 (0.319)	-0.58 (0.216)	-0.32 (0.231)	-0.90 (0.183)	
95% CI [2]	-0.90, 0.38	-1.02, -0.15	-0.78, 0.14	-1.26, -0.54	
Difference (95% CI) in CFB [2]		-0.32 (-0.99, 0.35)		-0.58 (-1.11, -0.05)	
Hedges'G (95% CI) in CFB		-0.25 (-0.86, 0.34)		-0.38 (-0.78, 0.01)	
p-value [3]		0.338		0.031	
					0.556

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	21	35	44	84	
Mean (StdDev)	2.1 (0.83)	1.8 (1.20)	2.5 (1.07)	2.5 (1.13)	
Median	2.0	2.0	2.0	3.0	
Min, Max	0, 3	0, 4	1, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	21	35	44	84	
Mean (StdDev)	1.3 (1.02)	1.3 (0.96)	2.0 (1.13)	1.8 (1.39)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C2D1 CFB					
n	20	34	43	82	
LS Mean (StdErr) [2]	-0.63 (0.272)	-0.52 (0.188)	-0.44 (0.172)	-0.66 (0.139)	
95% CI [2]	-1.17, -0.08	-0.89, -0.14	-0.78, -0.10	-0.94, -0.39	
Difference (95% CI) in CFB [2]		0.11 (-0.47, 0.68)		-0.23 (-0.63, 0.17)	
p-value [3]		0.706		0.259	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	18	33	45	76	
Mean (StdDev)	1.6 (0.92)	1.0 (0.95)	1.9 (1.18)	1.6 (1.16)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C3D1 CFB					
n	17	33	44	76	
LS Mean (StdErr) [2]	-0.44 (0.359)	-0.80 (0.238)	-0.49 (0.165)	-0.89 (0.136)	
95% CI [2]	-1.16, 0.28	-1.28, -0.32	-0.82, -0.16	-1.16, -0.62	
Difference (95% CI) in CFB [2]		-0.36 (-1.13, 0.40)		-0.40 (-0.79, -0.02)	
p-value [3]		0.347		0.040	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	17	33	39	79	
Mean (StdDev)	1.6 (1.00)	0.9 (0.98)	1.9 (1.19)	1.7 (1.29)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C4D1 CFB					
n	16	32	38	78	
LS Mean (StdErr) [2]	-0.51 (0.332)	-1.11 (0.228)	-0.55 (0.197)	-0.86 (0.152)	
95% CI [2]	-1.18, 0.15	-1.57, -0.65	-0.95, -0.16	-1.16, -0.56	
Difference (95% CI) in CFB [2]		-0.60 (-1.28, 0.09)		-0.31 (-0.75, 0.14)	
p-value [3]		0.086		0.177	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	32	41	77	
Mean (StdDev)	1.3 (1.20)	0.9 (1.08)	1.8 (1.36)	1.6 (1.25)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	18	30	41	75	
LS Mean (StdErr) [2]	-0.45 (0.336)	-1.02 (0.235)	-0.67 (0.202)	-0.96 (0.160)	
95% CI [2]	-1.13, 0.22	-1.49, -0.54	-1.08, -0.27	-1.28, -0.65	
Difference (95% CI) in CFB [2]		-0.56 (-1.28, 0.16)		-0.29 (-0.76, 0.18)	
p-value [3]		0.121		0.222	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	19	33	39	78	
Mean (StdDev)	1.6 (1.07)	0.8 (1.00)	1.8 (1.33)	1.6 (1.27)	
Median	2.0	0.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C6D1 CFB					
n	18	31	39	76	
LS Mean (StdErr) [2]	-0.53 (0.333)	-1.21 (0.231)	-0.59 (0.207)	-0.99 (0.161)	
95% CI [2]	-1.20, 0.14	-1.67, -0.74	-1.00, -0.18	-1.31, -0.67	
Difference (95% CI) in CFB [2]		-0.68 (-1.39, 0.03)		-0.40 (-0.88, 0.08)	
p-value [3]		0.059		0.099	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	18	35	40	76	
Mean (StdDev)	1.5 (0.99)	1.0 (1.03)	1.6 (1.34)	1.5 (1.32)	
Median	1.5	1.0	1.0	1.5	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C7D1 CFB					
n	17	33	40	74	
LS Mean (StdErr) [2]	-0.33 (0.309)	-0.77 (0.209)	-0.76 (0.216)	-0.95 (0.171)	
95% CI [2]	-0.95, 0.29	-1.19, -0.34	-1.18, -0.33	-1.29, -0.61	
Difference (95% CI) in CFB [2]		-0.44 (-1.08, 0.21)		-0.20 (-0.69, 0.30)	
Hedges'G (95% CI) in CFB		-0.35 (-0.97, 0.24)		-0.14 (-0.53, 0.25)	
p-value [3]		0.181		0.432	
					0.575

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	21	35	44	84	
Mean (StdDev)	2.3 (1.15)	2.3 (1.05)	2.8 (1.12)	2.9 (1.07)	
Median	2.0	3.0	3.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	21	35	44	84	
Mean (StdDev)	2.0 (1.24)	1.9 (1.09)	2.5 (1.05)	2.3 (1.22)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	20	34	43	82	
LS Mean (StdErr) [2]	-0.35 (0.254)	-0.41 (0.176)	-0.31 (0.157)	-0.63 (0.127)	
95% CI [2]	-0.86, 0.16	-0.76, -0.06	-0.62, -0.00	-0.89, -0.38	
Difference (95% CI) in CFB [2]		-0.06 (-0.60, 0.47)		-0.32 (-0.69, 0.04)	
p-value [3]		0.814		0.082	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	18	33	45	77	
Mean (StdDev)	1.9 (1.26)	1.6 (1.11)	2.4 (1.13)	2.3 (1.11)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	17	33	44	76	
LS Mean (StdErr) [2]	-0.44 (0.238)	-0.62 (0.157)	-0.44 (0.171)	-0.63 (0.142)	
95% CI [2]	-0.92, 0.04	-0.94, -0.30	-0.78, -0.11	-0.91, -0.35	
Difference (95% CI) in CFB [2]		-0.18 (-0.69, 0.33)		-0.19 (-0.59, 0.21)	
p-value [3]		0.476		0.351	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	17	33	39	80	
Mean (StdDev)	2.3 (1.21)	1.7 (1.04)	2.4 (1.12)	2.2 (1.19)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	16	32	38	79	
LS Mean (StdErr) [2]	-0.00 (0.278)	-0.65 (0.191)	-0.42 (0.203)	-0.74 (0.156)	
95% CI [2]	-0.56, 0.56	-1.03, -0.26	-0.83, -0.02	-1.05, -0.43	
Difference (95% CI) in CFB [2]		-0.65 (-1.22, -0.07)		-0.31 (-0.77, 0.15)	
p-value [3]		0.029		0.179	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	32	41	77	
Mean (StdDev)	1.9 (1.13)	1.8 (1.01)	2.4 (1.09)	2.2 (1.17)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	18	30	41	75	
LS Mean (StdErr) [2]	-0.35 (0.306)	-0.67 (0.214)	-0.43 (0.202)	-0.79 (0.160)	
95% CI [2]	-0.97, 0.26	-1.10, -0.24	-0.83, -0.03	-1.11, -0.48	
Difference (95% CI) in CFB [2]		-0.32 (-0.97, 0.34)		-0.36 (-0.83, 0.11)	
p-value [3]		0.335		0.129	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	19	33	39	78	
Mean (StdDev)	2.5 (1.12)	1.5 (0.87)	2.3 (1.30)	2.0 (1.22)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C6D1 CFB					
n	18	31	39	76	
LS Mean (StdErr) [2]	0.18 (0.282)	-0.89 (0.196)	-0.55 (0.212)	-0.92 (0.165)	
95% CI [2]	-0.39, 0.74	-1.29, -0.50	-0.97, -0.13	-1.25, -0.60	
Difference (95% CI) in CFB [2]		-1.07 (-1.67, -0.47)		-0.38 (-0.86, 0.11)	
p-value [3]		<0.001		0.131	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	18	35	40	76	
Mean (StdDev)	2.0 (1.28)	1.6 (0.95)	2.4 (1.21)	2.0 (1.23)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	17	33	40	74	
LS Mean (StdErr) [2]	-0.05 (0.286)	-0.65 (0.194)	-0.34 (0.204)	-0.90 (0.162)	
95% CI [2]	-0.63, 0.52	-1.04, -0.26	-0.75, 0.06	-1.22, -0.57	
Difference (95% CI) in CFB [2]		-0.60 (-1.20, -0.00)		-0.55 (-1.02, -0.09)	
Hedges'G (95% CI) in CFB		-0.52 (-1.16, 0.06)		-0.41 (-0.81, -0.02)	
p-value [3]		0.049		0.020	
					0.945

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	21	35	44	84	
Mean (StdDev)	2.0 (1.30)	1.5 (1.27)	2.3 (1.36)	2.3 (1.27)	
Median	2.0	1.0	2.5	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	21	35	44	84	
Mean (StdDev)	1.9 (1.11)	1.3 (1.27)	2.0 (1.37)	1.9 (1.31)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	20	34	43	82	
LS Mean (StdErr) [2]	-0.12 (0.258)	-0.24 (0.179)	-0.34 (0.161)	-0.41 (0.130)	
95% CI [2]	-0.63, 0.40	-0.60, 0.12	-0.66, -0.03	-0.67, -0.16	
Difference (95% CI) in CFB [2]		-0.12 (-0.67, 0.42)		-0.07 (-0.44, 0.30)	
p-value [3]		0.649		0.709	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	18	33	44	77	
Mean (StdDev)	1.7 (1.18)	1.2 (1.22)	1.8 (1.31)	1.6 (1.22)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	17	33	43	76	
LS Mean (StdErr) [2]	-0.40 (0.227)	-0.27 (0.150)	-0.62 (0.182)	-0.71 (0.149)	
95% CI [2]	-0.86, 0.06	-0.57, 0.04	-0.98, -0.26	-1.01, -0.41	
Difference (95% CI) in CFB [2]		0.13 (-0.35, 0.62)		-0.10 (-0.52, 0.33)	
p-value [3]		0.582		0.658	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	17	33	39	80	
Mean (StdDev)	1.7 (1.21)	1.2 (1.30)	1.8 (1.43)	1.7 (1.31)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	16	32	38	79	
LS Mean (StdErr) [2]	-0.61 (0.243)	-0.46 (0.167)	-0.53 (0.215)	-0.67 (0.165)	
95% CI [2]	-1.10, -0.12	-0.80, -0.13	-0.95, -0.10	-0.99, -0.34	
Difference (95% CI) in CFB [2]		0.15 (-0.36, 0.65)		-0.14 (-0.62, 0.35)	
p-value [3]		0.561		0.575	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	32	41	77	
Mean (StdDev)	1.6 (1.21)	1.1 (1.16)	1.8 (1.41)	1.5 (1.28)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	18	30	41	75	
LS Mean (StdErr) [2]	-0.30 (0.246)	-0.61 (0.172)	-0.68 (0.219)	-0.87 (0.174)	
95% CI [2]	-0.80, 0.19	-0.96, -0.26	-1.11, -0.25	-1.21, -0.52	
Difference (95% CI) in CFB [2]		-0.31 (-0.83, 0.22)		-0.18 (-0.69, 0.32)	
p-value [3]		0.248		0.472	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	19	33	39	78	
Mean (StdDev)	2.1 (1.22)	1.1 (1.13)	1.8 (1.50)	1.4 (1.23)	
Median	3.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	18	31	39	76	
LS Mean (StdErr) [2]	-0.36 (0.310)	-0.68 (0.216)	-0.42 (0.211)	-0.90 (0.164)	
95% CI [2]	-0.99, 0.26	-1.11, -0.24	-0.84, 0.00	-1.23, -0.58	
Difference (95% CI) in CFB [2]		-0.32 (-0.98, 0.34)		-0.49 (-0.97, 0.00)	
p-value [3]		0.337		0.051	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	18	35	40	76	
Mean (StdDev)	1.7 (1.41)	0.9 (1.16)	1.9 (1.35)	1.4 (1.35)	
Median	1.5	0.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	17	33	40	74	
LS Mean (StdErr) [2]	-0.49 (0.252)	-0.57 (0.171)	-0.39 (0.203)	-0.80 (0.161)	
95% CI [2]	-0.99, 0.02	-0.91, -0.22	-0.79, 0.01	-1.12, -0.48	
Difference (95% CI) in CFB [2]		-0.08 (-0.61, 0.45)		-0.41 (-0.87, 0.05)	
Hedges'G (95% CI) in CFB		-0.08 (-0.68, 0.52)		-0.30 (-0.70, 0.08)	
p-value [3]		0.762		0.082	
					0.535

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	21	35	44	84	
Mean (StdDev)	2.2 (0.94)	2.2 (0.94)	2.5 (1.05)	2.6 (1.11)	
Median	2.0	2.0	2.0	3.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	21	35	44	84	
Mean (StdDev)	1.8 (0.93)	1.5 (1.01)	2.0 (1.12)	2.0 (1.16)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C2D1 CFB					
n	20	34	43	82	
LS Mean (StdErr) [2]	-0.35 (0.230)	-0.74 (0.159)	-0.49 (0.188)	-0.70 (0.152)	
95% CI [2]	-0.81, 0.11	-1.06, -0.42	-0.86, -0.12	-1.00, -0.40	
Difference (95% CI) in CFB [2]		-0.38 (-0.87, 0.10)		-0.21 (-0.64, 0.23)	
p-value [3]		0.120		0.346	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	18	33	45	76	
Mean (StdDev)	1.8 (1.06)	1.4 (0.86)	2.1 (1.14)	1.8 (1.12)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	17	33	44	75	
LS Mean (StdErr) [2]	-0.46 (0.276)	-0.81 (0.183)	-0.44 (0.194)	-0.84 (0.161)	
95% CI [2]	-1.02, 0.10	-1.18, -0.45	-0.83, -0.06	-1.16, -0.52	
Difference (95% CI) in CFB [2]		-0.35 (-0.94, 0.24)		-0.40 (-0.85, 0.06)	
p-value [3]		0.235		0.086	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	17	33	39	80	
Mean (StdDev)	1.9 (1.11)	1.3 (0.98)	1.9 (1.13)	1.8 (1.17)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	16	32	38	79	
LS Mean (StdErr) [2]	-0.46 (0.290)	-1.05 (0.199)	-0.61 (0.206)	-0.84 (0.159)	
95% CI [2]	-1.04, 0.12	-1.45, -0.65	-1.01, -0.20	-1.15, -0.52	
Difference (95% CI) in CFB [2]		-0.59 (-1.19, 0.01)		-0.23 (-0.70, 0.24)	
p-value [3]		0.055		0.331	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	32	41	77	
Mean (StdDev)	1.7 (1.11)	1.2 (0.99)	1.9 (1.20)	1.7 (1.17)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C5D1 CFB					
n	18	30	41	75	
LS Mean (StdErr) [2]	-0.36 (0.305)	-1.19 (0.213)	-0.69 (0.213)	-0.98 (0.169)	
95% CI [2]	-0.97, 0.26	-1.62, -0.76	-1.11, -0.27	-1.31, -0.64	
Difference (95% CI) in CFB [2]		-0.83 (-1.48, -0.18)		-0.29 (-0.78, 0.20)	
p-value [3]		0.014		0.243	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	19	33	39	78	
Mean (StdDev)	2.0 (0.94)	1.2 (1.06)	1.9 (1.25)	1.6 (1.16)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	18	31	39	76	
LS Mean (StdErr) [2]	-0.22 (0.277)	-1.16 (0.193)	-0.66 (0.214)	-1.12 (0.166)	
95% CI [2]	-0.78, 0.34	-1.55, -0.77	-1.08, -0.23	-1.45, -0.79	
Difference (95% CI) in CFB [2]		-0.94 (-1.53, -0.35)		-0.46 (-0.96, 0.03)	
p-value [3]		0.002		0.066	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	18	35	40	76	
Mean (StdDev)	1.7 (1.18)	1.1 (1.00)	2.0 (1.32)	1.7 (1.36)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	17	33	40	74	
LS Mean (StdErr) [2]	-0.27 (0.295)	-1.07 (0.200)	-0.50 (0.246)	-0.96 (0.195)	
95% CI [2]	-0.86, 0.32	-1.47, -0.67	-0.99, -0.02	-1.35, -0.58	
Difference (95% CI) in CFB [2]		-0.80 (-1.42, -0.19)		-0.46 (-1.02, 0.10)	
Hedges'G (95% CI) in CFB		-0.68 (-1.32, -0.09)		-0.28 (-0.68, 0.11)	
p-value [3]		0.012		0.108	
					0.476

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	21	35	43	84	
Mean (StdDev)	1.8 (1.08)	1.8 (1.06)	2.2 (1.32)	2.4 (1.18)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	21	35	44	84	
Mean (StdDev)	1.6 (1.16)	1.5 (1.15)	2.0 (1.26)	1.9 (1.18)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	20	34	42	82	
LS Mean (StdErr) [2]	-0.25 (0.250)	-0.34 (0.173)	-0.17 (0.178)	-0.53 (0.143)	
95% CI [2]	-0.75, 0.25	-0.69, 0.00	-0.52, 0.19	-0.81, -0.25	
Difference (95% CI) in CFB [2]		-0.09 (-0.62, 0.44)		-0.36 (-0.78, 0.05)	
p-value [3]		0.725		0.081	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	18	33	45	77	
Mean (StdDev)	1.8 (1.11)	1.2 (0.99)	1.8 (1.24)	1.8 (1.10)	
Median	1.5	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	17	33	43	76	
LS Mean (StdErr) [2]	0.05 (0.216)	-0.58 (0.143)	-0.33 (0.177)	-0.64 (0.145)	
95% CI [2]	-0.39, 0.48	-0.87, -0.29	-0.68, 0.02	-0.93, -0.35	
Difference (95% CI) in CFB [2]		-0.63 (-1.09, -0.17)		-0.32 (-0.73, 0.10)	
p-value [3]		0.008		0.132	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	17	33	39	80	
Mean (StdDev)	1.7 (1.21)	1.3 (1.16)	1.8 (1.27)	1.8 (1.27)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	16	32	37	79	
LS Mean (StdErr) [2]	-0.02 (0.272)	-0.54 (0.187)	-0.35 (0.214)	-0.71 (0.163)	
95% CI [2]	-0.57, 0.53	-0.92, -0.17	-0.77, 0.07	-1.04, -0.39	
Difference (95% CI) in CFB [2]		-0.52 (-1.09, 0.04)		-0.36 (-0.85, 0.12)	
p-value [3]		0.067		0.138	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	32	41	77	
Mean (StdDev)	1.5 (0.96)	1.3 (1.11)	1.8 (1.17)	1.6 (1.16)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C5D1 CFB					
n	18	30	40	75	
LS Mean (StdErr) [2]	0.04 (0.227)	-0.62 (0.158)	-0.44 (0.212)	-0.81 (0.167)	
95% CI [2]	-0.42, 0.49	-0.94, -0.30	-0.86, -0.02	-1.14, -0.48	
Difference (95% CI) in CFB [2]		-0.65 (-1.14, -0.17)		-0.36 (-0.85, 0.13)	
p-value [3]		0.009		0.147	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	19	33	39	78	
Mean (StdDev)	1.9 (0.97)	1.1 (1.03)	1.7 (1.32)	1.7 (1.26)	
Median	2.0	1.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	18	31	38	76	
LS Mean (StdErr) [2]	0.14 (0.244)	-0.85 (0.169)	-0.43 (0.219)	-0.85 (0.169)	
95% CI [2]	-0.35, 0.63	-1.19, -0.51	-0.87, 0.00	-1.18, -0.51	
Difference (95% CI) in CFB [2]		-0.99 (-1.51, -0.47)		-0.42 (-0.92, 0.09)	
p-value [3]		<0.001		0.106	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	18	35	40	76	
Mean (StdDev)	1.6 (1.15)	1.2 (1.06)	1.8 (1.20)	1.7 (1.33)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	17	33	39	74	
LS Mean (StdErr) [2]	0.08 (0.254)	-0.53 (0.172)	-0.27 (0.229)	-0.65 (0.180)	
95% CI [2]	-0.43, 0.59	-0.88, -0.19	-0.72, 0.19	-1.01, -0.30	
Difference (95% CI) in CFB [2]		-0.61 (-1.15, -0.08)		-0.39 (-0.91, 0.14)	
Hedges'G (95% CI) in CFB		-0.60 (-1.24, -0.01)		-0.25 (-0.65, 0.13)	
p-value [3]		0.025		0.146	
					0.530

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ism-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	12	25	53	94	
Mean (StdDev)	2.8 (0.75)	2.4 (0.77)	2.8 (1.20)	2.3 (1.17)	
Median	3.0	2.0	3.0	2.0	
Min, Max	2, 4	1, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	52	94	
Mean (StdDev)	2.1 (0.86)	1.8 (1.08)	2.4 (1.07)	1.6 (0.85)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	12	24	51	92	
LS Mean (StdErr) [2]	-0.61 (0.425)	-0.57 (0.269)	-0.35 (0.143)	-0.59 (0.113)	
95% CI [2]	-1.47, 0.26	-1.11, -0.02	-0.63, -0.07	-0.81, -0.37	
Difference (95% CI) in CFB [2]		0.04 (-0.93, 1.01)		-0.24 (-0.58, 0.11)	
p-value [3]		0.930		0.182	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	24	50	86	
Mean (StdDev)	1.7 (0.75)	1.9 (0.95)	2.2 (1.18)	1.4 (0.91)	
Median	2.0	2.0	2.5	1.0	
Min, Max	1, 3	0, 4	0, 4	0, 4	
C3D1 CFB					
n	12	24	49	85	
LS Mean (StdErr) [2]	-1.05 (0.345)	-0.60 (0.218)	-0.53 (0.169)	-0.80 (0.134)	
95% CI [2]	-1.75, -0.35	-1.04, -0.15	-0.87, -0.20	-1.06, -0.53	
Difference (95% CI) in CFB [2]		0.45 (-0.34, 1.24)		-0.26 (-0.67, 0.15)	
p-value [3]		0.253		0.205	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	11	22	45	91	
Mean (StdDev)	1.9 (0.83)	1.6 (1.22)	2.3 (1.13)	1.4 (0.97)	
Median	2.0	1.0	2.0	1.0	
Min, Max	1, 3	0, 4	0, 4	0, 4	
C4D1 CFB					
n	10	22	44	89	
LS Mean (StdErr) [2]	-0.84 (0.406)	-0.97 (0.257)	-0.39 (0.181)	-0.85 (0.134)	
95% CI [2]	-1.67, -0.01	-1.50, -0.45	-0.75, -0.03	-1.11, -0.58	
Difference (95% CI) in CFB [2]		-0.13 (-1.04, 0.77)		-0.45 (-0.88, -0.02)	
p-value [3]		0.764		0.039	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	25	48	83	
Mean (StdDev)	1.7 (0.78)	1.6 (1.00)	2.4 (1.24)	1.3 (0.96)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C5D1 CFB					
n	11	24	48	80	
LS Mean (StdErr) [2]	-1.19 (0.386)	-0.83 (0.242)	-0.21 (0.177)	-0.86 (0.145)	
95% CI [2]	-1.98, -0.41	-1.33, -0.34	-0.56, 0.14	-1.14, -0.57	
Difference (95% CI) in CFB [2]		0.36 (-0.50, 1.22)		-0.65 (-1.08, -0.21)	
p-value [3]		0.401		0.004	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	25	46	86	
Mean (StdDev)	1.6 (0.79)	1.6 (1.08)	2.3 (1.25)	1.4 (1.02)	
Median	2.0	2.0	3.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C6D1 CFB					
n	11	24	46	83	
LS Mean (StdErr) [2]	-1.21 (0.427)	-0.80 (0.267)	-0.40 (0.173)	-0.83 (0.136)	
95% CI [2]	-2.08, -0.34	-1.35, -0.26	-0.74, -0.06	-1.10, -0.56	
Difference (95% CI) in CFB [2]		0.41 (-0.55, 1.36)		-0.43 (-0.85, -0.01)	
p-value [3]		0.390		0.046	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	11	24	47	87	
Mean (StdDev)	2.0 (1.00)	1.5 (1.06)	2.4 (1.17)	1.3 (0.92)	
Median	2.0	1.0	3.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C7D1 CFB					
n	10	23	47	84	
LS Mean (StdErr) [2]	-0.88 (0.400)	-0.90 (0.245)	-0.30 (0.162)	-0.86 (0.126)	
95% CI [2]	-1.70, -0.07	-1.40, -0.40	-0.63, 0.02	-1.10, -0.61	
Difference (95% CI) in CFB [2]		-0.02 (-0.92, 0.88)		-0.55 (-0.94, -0.16)	
Hedges'G (95% CI) in CFB		-0.02 (-0.79, 0.76)		-0.48 (-0.85, -0.12)	
p-value [3]		0.966		0.006	
					0.501

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	12	25	53	94	
Mean (StdDev)	2.3 (0.98)	2.2 (1.11)	2.5 (1.20)	2.1 (1.15)	
Median	3.0	2.0	3.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	52	94	
Mean (StdDev)	2.0 (1.15)	1.5 (1.05)	2.3 (1.12)	1.4 (0.98)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	12	24	51	92	
LS Mean (StdErr) [2]	0.07 (0.428)	-0.55 (0.271)	-0.27 (0.156)	-0.61 (0.124)	
95% CI [2]	-0.80, 0.95	-1.10, -0.00	-0.58, 0.04	-0.85, -0.36	
Difference (95% CI) in CFB [2]		-0.63 (-1.60, 0.35)		-0.34 (-0.73, 0.04)	
p-value [3]		0.200		0.078	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	24	50	86	
Mean (StdDev)	1.8 (1.01)	1.6 (0.93)	2.2 (1.27)	1.4 (1.02)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C3D1 CFB					
n	12	24	49	85	
LS Mean (StdErr) [2]	-0.38 (0.387)	-0.56 (0.245)	-0.29 (0.178)	-0.62 (0.140)	
95% CI [2]	-1.17, 0.41	-1.06, -0.07	-0.64, 0.06	-0.90, -0.34	
Difference (95% CI) in CFB [2]		-0.18 (-1.07, 0.70)		-0.33 (-0.76, 0.10)	
p-value [3]		0.673		0.127	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	11	22	45	91	
Mean (StdDev)	1.8 (0.98)	1.6 (1.09)	2.3 (1.07)	1.2 (1.02)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C4D1 CFB					
n	10	22	44	89	
LS Mean (StdErr) [2]	-0.43 (0.448)	-0.61 (0.283)	-0.22 (0.174)	-0.80 (0.129)	
95% CI [2]	-1.35, 0.48	-1.19, -0.03	-0.56, 0.13	-1.05, -0.54	
Difference (95% CI) in CFB [2]		-0.17 (-1.18, 0.83)		-0.58 (-1.00, -0.17)	
p-value [3]		0.727		0.006	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	25	48	83	
Mean (StdDev)	1.8 (0.87)	1.6 (0.87)	2.2 (1.35)	1.3 (1.01)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C5D1 CFB					
n	11	24	48	80	
LS Mean (StdErr) [2]	-0.34 (0.384)	-0.49 (0.241)	-0.27 (0.177)	-0.71 (0.146)	
95% CI [2]	-1.12, 0.45	-0.98, -0.00	-0.62, 0.08	-1.00, -0.42	
Difference (95% CI) in CFB [2]		-0.16 (-1.02, 0.70)		-0.44 (-0.88, -0.00)	
p-value [3]		0.713		0.050	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	25	46	86	
Mean (StdDev)	1.8 (0.94)	1.6 (1.08)	2.2 (1.23)	1.4 (1.09)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C6D1 CFB					
n	11	24	46	83	
LS Mean (StdErr) [2]	-0.32 (0.422)	-0.52 (0.264)	-0.21 (0.179)	-0.65 (0.141)	
95% CI [2]	-1.18, 0.54	-1.06, 0.02	-0.57, 0.14	-0.93, -0.37	
Difference (95% CI) in CFB [2]		-0.21 (-1.15, 0.74)		-0.44 (-0.88, -0.00)	
p-value [3]		0.661		0.049	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	11	24	47	87	
Mean (StdDev)	1.8 (0.87)	1.7 (1.05)	2.2 (1.25)	1.3 (1.09)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C7D1 CFB					
n	10	23	47	84	
LS Mean (StdErr) [2]	-0.34 (0.430)	-0.41 (0.263)	-0.17 (0.182)	-0.63 (0.141)	
95% CI [2]	-1.22, 0.54	-0.95, 0.12	-0.53, 0.19	-0.91, -0.35	
Difference (95% CI) in CFB [2]		-0.07 (-1.04, 0.90)		-0.46 (-0.90, -0.02)	
Hedges'G (95% CI) in CFB		-0.05 (-0.83, 0.72)		-0.36 (-0.73, 0.00)	
p-value [3]		0.883		0.042	
					0.579

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	12	25	53	94	
Mean (StdDev)	2.3 (1.06)	2.6 (1.04)	2.3 (1.17)	2.3 (1.09)	
Median	2.5	3.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	52	94	
Mean (StdDev)	2.4 (1.04)	2.0 (1.24)	2.0 (1.10)	1.8 (1.03)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	12	24	51	92	
LS Mean (StdErr) [2]	0.15 (0.381)	-0.55 (0.241)	-0.30 (0.137)	-0.41 (0.108)	
95% CI [2]	-0.63, 0.92	-1.04, -0.06	-0.57, -0.03	-0.62, -0.19	
Difference (95% CI) in CFB [2]		-0.70 (-1.56, 0.17)		-0.11 (-0.44, 0.23)	
p-value [3]		0.113		0.531	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	24	50	86	
Mean (StdDev)	2.0 (1.15)	2.0 (1.16)	2.0 (1.01)	1.7 (1.07)	
Median	2.0	2.5	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	12	24	49	85	
LS Mean (StdErr) [2]	-0.18 (0.391)	-0.52 (0.248)	-0.20 (0.160)	-0.44 (0.127)	
95% CI [2]	-0.97, 0.62	-1.02, -0.02	-0.52, 0.12	-0.69, -0.19	
Difference (95% CI) in CFB [2]		-0.34 (-1.23, 0.55)		-0.24 (-0.63, 0.15)	
p-value [3]		0.441		0.221	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	11	22	45	91	
Mean (StdDev)	2.2 (1.08)	2.0 (1.17)	2.1 (1.16)	1.7 (0.99)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	10	22	44	89	
LS Mean (StdErr) [2]	-0.04 (0.389)	-0.52 (0.246)	-0.18 (0.174)	-0.55 (0.129)	
95% CI [2]	-0.83, 0.76	-1.02, -0.01	-0.52, 0.17	-0.80, -0.29	
Difference (95% CI) in CFB [2]		-0.48 (-1.35, 0.39)		-0.37 (-0.79, 0.04)	
p-value [3]		0.268		0.076	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	25	48	83	
Mean (StdDev)	1.9 (1.16)	1.8 (1.20)	2.1 (1.26)	1.7 (1.05)	
Median	1.5	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	11	24	48	80	
LS Mean (StdErr) [2]	-0.13 (0.464)	-0.69 (0.290)	-0.16 (0.172)	-0.44 (0.141)	
95% CI [2]	-1.07, 0.82	-1.28, -0.09	-0.50, 0.18	-0.72, -0.16	
Difference (95% CI) in CFB [2]		-0.56 (-1.60, 0.48)		-0.28 (-0.70, 0.15)	
p-value [3]		0.280		0.197	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	25	46	86	
Mean (StdDev)	1.9 (1.08)	1.9 (1.24)	1.9 (1.23)	1.6 (1.11)	
Median	1.5	2.0	2.0	1.5	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	11	24	46	83	
LS Mean (StdErr) [2]	-0.26 (0.417)	-0.61 (0.261)	-0.30 (0.174)	-0.59 (0.137)	
95% CI [2]	-1.11, 0.59	-1.15, -0.08	-0.64, 0.04	-0.86, -0.32	
Difference (95% CI) in CFB [2]		-0.36 (-1.29, 0.58)		-0.29 (-0.72, 0.13)	
p-value [3]		0.442		0.176	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	11	24	47	87	
Mean (StdDev)	2.0 (1.00)	1.8 (1.20)	1.9 (1.16)	1.6 (1.09)	
Median	2.0	2.0	2.0	1.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	10	23	47	84	
LS Mean (StdErr) [2]	-0.03 (0.507)	-0.71 (0.310)	-0.39 (0.175)	-0.59 (0.136)	
95% CI [2]	-1.07, 1.00	-1.35, -0.08	-0.73, -0.04	-0.86, -0.32	
Difference (95% CI) in CFB [2]		-0.68 (-1.82, 0.46)		-0.20 (-0.63, 0.22)	
Hedges'G (95% CI) in CFB		-0.44 (-1.25, 0.31)		-0.16 (-0.53, 0.19)	
p-value [3]		0.234		0.343	
					0.317

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	12	25	53	94	
Mean (StdDev)	2.3 (1.07)	1.9 (1.35)	2.1 (1.23)	2.2 (1.18)	
Median	2.5	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	24	52	94	
Mean (StdDev)	1.8 (1.24)	1.8 (1.22)	1.7 (1.16)	1.5 (1.10)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	12	23	51	92	
LS Mean (StdErr) [2]	-0.52 (0.480)	-0.15 (0.312)	-0.35 (0.152)	-0.72 (0.120)	
95% CI [2]	-1.50, 0.46	-0.79, 0.49	-0.65, -0.05	-0.96, -0.49	
Difference (95% CI) in CFB [2]		0.37 (-0.72, 1.46)		-0.37 (-0.74, -0.00)	
p-value [3]		0.497		0.050	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	24	50	86	
Mean (StdDev)	1.5 (1.27)	1.7 (1.43)	1.8 (1.30)	1.5 (1.06)	
Median	1.0	1.5	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	12	24	49	85	
LS Mean (StdErr) [2]	-0.61 (0.435)	-0.12 (0.275)	-0.20 (0.180)	-0.72 (0.143)	
95% CI [2]	-1.49, 0.28	-0.68, 0.44	-0.55, 0.16	-1.00, -0.44	
Difference (95% CI) in CFB [2]		0.48 (-0.51, 1.47)		-0.52 (-0.96, -0.08)	
p-value [3]		0.329		0.020	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	11	22	45	91	
Mean (StdDev)	1.8 (1.17)	1.6 (1.22)	1.8 (1.24)	1.5 (1.19)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	10	22	44	89	
LS Mean (StdErr) [2]	-0.75 (0.409)	-0.25 (0.259)	-0.38 (0.180)	-0.74 (0.133)	
95% CI [2]	-1.59, 0.09	-0.78, 0.28	-0.74, -0.03	-1.00, -0.48	
Difference (95% CI) in CFB [2]		0.50 (-0.42, 1.42)		-0.36 (-0.79, 0.07)	
p-value [3]		0.274		0.099	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	25	48	83	
Mean (StdDev)	1.7 (0.98)	1.6 (1.15)	1.9 (1.13)	1.4 (1.17)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	11	24	48	80	
LS Mean (StdErr) [2]	-0.68 (0.405)	-0.23 (0.254)	-0.15 (0.179)	-0.89 (0.147)	
95% CI [2]	-1.50, 0.15	-0.75, 0.29	-0.51, 0.20	-1.19, -0.60	
Difference (95% CI) in CFB [2]		0.45 (-0.46, 1.36)		-0.74 (-1.18, -0.30)	
p-value [3]		0.320		0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	25	46	86	
Mean (StdDev)	1.7 (1.30)	1.6 (1.22)	1.8 (1.17)	1.3 (1.12)	
Median	1.5	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	11	24	46	83	
LS Mean (StdErr) [2]	-0.66 (0.450)	-0.26 (0.282)	-0.22 (0.176)	-0.84 (0.139)	
95% CI [2]	-1.58, 0.26	-0.83, 0.31	-0.57, 0.12	-1.11, -0.56	
Difference (95% CI) in CFB [2]		0.40 (-0.61, 1.41)		-0.62 (-1.05, -0.19)	
p-value [3]		0.424		0.005	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	11	24	47	87	
Mean (StdDev)	1.8 (1.17)	1.6 (1.35)	1.7 (1.09)	1.4 (1.21)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	10	23	47	84	
LS Mean (StdErr) [2]	-0.41 (0.509)	-0.18 (0.312)	-0.27 (0.172)	-0.75 (0.133)	
95% CI [2]	-1.45, 0.63	-0.82, 0.46	-0.61, 0.07	-1.01, -0.49	
Difference (95% CI) in CFB [2]		0.23 (-0.91, 1.38)		-0.48 (-0.90, -0.07)	
Hedges'G (95% CI) in CFB		0.15 (-0.61, 0.93)		-0.40 (-0.77, -0.04)	
p-value [3]		0.679		0.024	
					0.249

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	12	25	53	94	
Mean (StdDev)	3.2 (0.72)	3.4 (0.87)	3.1 (0.96)	3.2 (0.87)	
Median	3.0	4.0	3.0	3.0	
Min, Max	2, 4	1, 4	1, 4	1, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	52	94	
Mean (StdDev)	2.9 (0.95)	2.8 (1.15)	2.8 (0.96)	2.7 (1.06)	
Median	3.0	3.0	3.0	3.0	
Min, Max	2, 4	0, 4	1, 4	0, 4	
C2D1 CFB					
n	12	24	51	92	
LS Mean (StdErr) [2]	-0.07 (0.330)	-0.57 (0.209)	-0.38 (0.134)	-0.53 (0.106)	
95% CI [2]	-0.74, 0.60	-0.99, -0.15	-0.65, -0.12	-0.74, -0.32	
Difference (95% CI) in CFB [2]		-0.50 (-1.25, 0.25)		-0.15 (-0.47, 0.18)	
p-value [3]		0.182		0.381	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	24	50	86	
Mean (StdDev)	2.7 (1.38)	2.8 (1.15)	2.7 (1.04)	2.5 (1.07)	
Median	3.0	3.0	3.0	3.0	
Min, Max	0, 4	1, 4	0, 4	0, 4	
C3D1 CFB					
n	12	24	49	85	
LS Mean (StdErr) [2]	-0.49 (0.411)	-0.62 (0.260)	-0.46 (0.153)	-0.76 (0.121)	
95% CI [2]	-1.33, 0.34	-1.15, -0.09	-0.76, -0.15	-1.00, -0.52	
Difference (95% CI) in CFB [2]		-0.13 (-1.07, 0.81)		-0.30 (-0.67, 0.07)	
p-value [3]		0.778		0.108	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	11	22	45	91	
Mean (StdDev)	2.7 (1.35)	2.6 (1.09)	2.8 (1.08)	2.5 (1.12)	
Median	3.0	3.0	3.0	3.0	
Min, Max	1, 4	1, 4	1, 4	0, 4	
C4D1 CFB					
n	10	22	44	89	
LS Mean (StdErr) [2]	-0.27 (0.419)	-0.71 (0.265)	-0.46 (0.170)	-0.69 (0.126)	
95% CI [2]	-1.13, 0.58	-1.26, -0.17	-0.80, -0.12	-0.93, -0.44	
Difference (95% CI) in CFB [2]		-0.44 (-1.38, 0.50)		-0.23 (-0.63, 0.18)	
p-value [3]		0.343		0.268	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	25	48	83	
Mean (StdDev)	2.8 (1.14)	2.6 (1.11)	2.7 (1.24)	2.3 (1.16)	
Median	3.0	3.0	3.0	2.0	
Min, Max	1, 4	1, 4	0, 4	0, 4	
C5D1 CFB					
n	11	24	48	80	
LS Mean (StdErr) [2]	-0.36 (0.368)	-0.71 (0.231)	-0.46 (0.168)	-0.87 (0.138)	
95% CI [2]	-1.11, 0.39	-1.18, -0.24	-0.79, -0.13	-1.15, -0.60	
Difference (95% CI) in CFB [2]		-0.35 (-1.18, 0.47)		-0.41 (-0.82, 0.00)	
p-value [3]		0.391		0.052	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	25	46	86	
Mean (StdDev)	2.3 (1.14)	2.5 (1.33)	2.7 (1.08)	2.3 (1.15)	
Median	2.0	2.0	3.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	11	24	46	83	
LS Mean (StdErr) [2]	-0.89 (0.406)	-0.91 (0.254)	-0.42 (0.173)	-0.81 (0.136)	
95% CI [2]	-1.72, -0.07	-1.43, -0.39	-0.76, -0.08	-1.08, -0.55	
Difference (95% CI) in CFB [2]		-0.02 (-0.92, 0.89)		-0.40 (-0.82, 0.03)	
p-value [3]		0.970		0.066	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	11	24	47	87	
Mean (StdDev)	2.3 (1.10)	2.7 (1.17)	2.7 (1.08)	2.3 (1.10)	
Median	2.0	3.0	3.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	10	23	47	84	
LS Mean (StdErr) [2]	-0.65 (0.418)	-0.64 (0.256)	-0.47 (0.163)	-0.83 (0.127)	
95% CI [2]	-1.50, 0.21	-1.16, -0.11	-0.79, -0.14	-1.08, -0.58	
Difference (95% CI) in CFB [2]		0.01 (-0.93, 0.95)		-0.36 (-0.76, 0.03)	
Hedges'G (95% CI) in CFB		0.01 (-0.77, 0.78)		-0.31 (-0.68, 0.04)	
p-value [3]		0.985		0.073	
					0.377

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	12	25	53	94	
Mean (StdDev)	2.7 (1.07)	2.0 (0.96)	2.0 (1.12)	2.2 (1.06)	
Median	3.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	52	94	
Mean (StdDev)	2.2 (1.01)	1.8 (1.03)	1.9 (1.11)	1.9 (0.98)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	12	24	51	92	
LS Mean (StdErr) [2]	-0.49 (0.295)	-0.19 (0.187)	-0.10 (0.132)	-0.34 (0.104)	
95% CI [2]	-1.09, 0.11	-0.57, 0.19	-0.36, 0.16	-0.55, -0.14	
Difference (95% CI) in CFB [2]		0.30 (-0.37, 0.97)		-0.24 (-0.56, 0.08)	
p-value [3]		0.373		0.142	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	24	50	86	
Mean (StdDev)	2.0 (1.22)	1.7 (0.95)	1.8 (1.09)	1.6 (0.98)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	12	24	49	85	
LS Mean (StdErr) [2]	-0.78 (0.342)	-0.32 (0.217)	-0.16 (0.153)	-0.61 (0.121)	
95% CI [2]	-1.47, -0.08	-0.77, 0.12	-0.46, 0.14	-0.85, -0.37	
Difference (95% CI) in CFB [2]		0.45 (-0.33, 1.23)		-0.45 (-0.82, -0.08)	
p-value [3]		0.248		0.018	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	11	22	45	91	
Mean (StdDev)	2.5 (1.13)	1.8 (1.07)	1.8 (1.17)	1.8 (1.18)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	10	22	44	89	
LS Mean (StdErr) [2]	-0.12 (0.403)	-0.24 (0.255)	-0.28 (0.168)	-0.46 (0.124)	
95% CI [2]	-0.95, 0.70	-0.76, 0.28	-0.61, 0.06	-0.70, -0.21	
Difference (95% CI) in CFB [2]		-0.12 (-1.02, 0.79)		-0.18 (-0.58, 0.22)	
p-value [3]		0.796		0.373	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	25	48	83	
Mean (StdDev)	2.2 (1.34)	1.7 (1.10)	1.9 (1.22)	1.7 (1.13)	
Median	2.5	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	11	24	48	80	
LS Mean (StdErr) [2]	-0.42 (0.380)	-0.24 (0.238)	-0.20 (0.152)	-0.51 (0.125)	
95% CI [2]	-1.20, 0.35	-0.72, 0.25	-0.50, 0.10	-0.76, -0.26	
Difference (95% CI) in CFB [2]		0.19 (-0.66, 1.04)		-0.31 (-0.68, 0.07)	
p-value [3]		0.657		0.105	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	25	46	86	
Mean (StdDev)	2.0 (1.21)	1.8 (1.31)	1.9 (1.07)	1.6 (1.10)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	11	24	46	83	
LS Mean (StdErr) [2]	-0.86 (0.350)	-0.21 (0.219)	-0.22 (0.148)	-0.65 (0.117)	
95% CI [2]	-1.57, -0.14	-0.66, 0.23	-0.52, 0.07	-0.88, -0.41	
Difference (95% CI) in CFB [2]		0.64 (-0.14, 1.43)		-0.42 (-0.79, -0.06)	
p-value [3]		0.105		0.022	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	11	24	47	87	
Mean (StdDev)	1.8 (1.08)	1.7 (1.13)	1.8 (1.11)	1.6 (1.09)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	10	23	47	84	
LS Mean (StdErr) [2]	-0.58 (0.357)	-0.21 (0.218)	-0.34 (0.148)	-0.65 (0.115)	
95% CI [2]	-1.31, 0.15	-0.66, 0.24	-0.64, -0.05	-0.87, -0.42	
Difference (95% CI) in CFB [2]		0.37 (-0.44, 1.17)		-0.30 (-0.66, 0.05)	
Hedges'G (95% CI) in CFB		0.34 (-0.42, 1.14)		-0.29 (-0.66, 0.07)	
p-value [3]		0.356		0.096	
					0.104

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	12	25	53	94	
Mean (StdDev)	2.6 (1.31)	2.8 (1.23)	2.8 (1.14)	2.8 (1.11)	
Median	3.0	3.0	3.0	3.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	24	52	94	
Mean (StdDev)	1.9 (1.19)	2.3 (1.40)	2.4 (1.05)	2.2 (1.02)	
Median	2.0	2.5	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	12	23	51	92	
LS Mean (StdErr) [2]	-0.53 (0.362)	-0.23 (0.235)	-0.31 (0.124)	-0.55 (0.098)	
95% CI [2]	-1.27, 0.20	-0.70, 0.25	-0.56, -0.06	-0.75, -0.36	
Difference (95% CI) in CFB [2]		0.31 (-0.51, 1.13)		-0.24 (-0.55, 0.06)	
p-value [3]		0.449		0.118	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	24	50	86	
Mean (StdDev)	2.1 (1.38)	2.1 (1.39)	2.3 (1.08)	2.2 (1.17)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	12	24	49	85	
LS Mean (StdErr) [2]	-0.57 (0.418)	-0.62 (0.265)	-0.50 (0.156)	-0.59 (0.123)	
95% CI [2]	-1.42, 0.28	-1.16, -0.08	-0.81, -0.19	-0.84, -0.35	
Difference (95% CI) in CFB [2]		-0.05 (-1.00, 0.90)		-0.09 (-0.47, 0.29)	
p-value [3]		0.914		0.633	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	11	22	45	91	
Mean (StdDev)	2.3 (1.10)	2.4 (1.37)	2.5 (1.18)	2.1 (1.19)	
Median	2.0	3.0	3.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	10	22	44	89	
LS Mean (StdErr) [2]	-0.48 (0.479)	-0.54 (0.303)	-0.29 (0.178)	-0.59 (0.132)	
95% CI [2]	-1.46, 0.50	-1.16, 0.08	-0.64, 0.06	-0.85, -0.33	
Difference (95% CI) in CFB [2]		-0.06 (-1.13, 1.02)		-0.30 (-0.72, 0.13)	
p-value [3]		0.913		0.168	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	25	48	83	
Mean (StdDev)	2.6 (1.00)	2.2 (1.31)	2.4 (1.17)	2.3 (1.16)	
Median	3.0	2.0	3.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	11	24	48	80	
LS Mean (StdErr) [2]	-0.11 (0.387)	-0.59 (0.242)	-0.34 (0.156)	-0.55 (0.128)	
95% CI [2]	-0.90, 0.68	-1.08, -0.10	-0.64, -0.03	-0.80, -0.29	
Difference (95% CI) in CFB [2]		-0.48 (-1.35, 0.38)		-0.21 (-0.60, 0.17)	
p-value [3]		0.264		0.276	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	25	46	86	
Mean (StdDev)	2.3 (1.15)	2.2 (1.37)	2.5 (1.24)	2.1 (1.16)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	11	24	46	83	
LS Mean (StdErr) [2]	-0.34 (0.394)	-0.62 (0.246)	-0.31 (0.171)	-0.70 (0.135)	
95% CI [2]	-1.14, 0.46	-1.12, -0.11	-0.65, 0.03	-0.97, -0.43	
Difference (95% CI) in CFB [2]		-0.28 (-1.16, 0.61)		-0.39 (-0.81, 0.03)	
p-value [3]		0.529		0.070	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	11	24	47	87	
Mean (StdDev)	1.9 (1.14)	2.3 (1.36)	2.3 (1.20)	2.1 (1.13)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	10	23	47	84	
LS Mean (StdErr) [2]	-0.23 (0.363)	-0.26 (0.222)	-0.39 (0.164)	-0.59 (0.127)	
95% CI [2]	-0.97, 0.51	-0.71, 0.20	-0.71, -0.07	-0.84, -0.34	
Difference (95% CI) in CFB [2]		-0.03 (-0.84, 0.79)		-0.20 (-0.60, 0.20)	
Hedges'G (95% CI) in CFB		-0.02 (-0.80, 0.75)		-0.17 (-0.54, 0.18)	
p-value [3]		0.949		0.317	
					0.502

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	12	25	53	94	
Mean (StdDev)	2.5 (1.31)	2.8 (1.07)	2.2 (1.09)	2.6 (1.07)	
Median	2.0	3.0	2.0	3.0	
Min, Max	0, 4	1, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	51	94	
Mean (StdDev)	2.2 (1.21)	2.2 (1.30)	2.1 (1.21)	2.0 (1.11)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	12	24	50	92	
LS Mean (StdErr) [2]	-0.00 (0.319)	-0.44 (0.202)	-0.15 (0.129)	-0.61 (0.101)	
95% CI [2]	-0.65, 0.65	-0.85, -0.03	-0.41, 0.10	-0.81, -0.41	
Difference (95% CI) in CFB [2]		-0.44 (-1.17, 0.29)		-0.45 (-0.77, -0.14)	
p-value [3]		0.226		0.005	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	24	50	86	
Mean (StdDev)	2.5 (1.27)	2.3 (1.26)	2.0 (1.16)	1.8 (1.14)	
Median	2.0	2.5	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	12	24	49	85	
LS Mean (StdErr) [2]	0.19 (0.294)	-0.50 (0.186)	-0.28 (0.129)	-0.86 (0.102)	
95% CI [2]	-0.40, 0.79	-0.88, -0.12	-0.54, -0.03	-1.06, -0.65	
Difference (95% CI) in CFB [2]		-0.69 (-1.36, -0.02)		-0.57 (-0.89, -0.26)	
p-value [3]		0.043		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	11	22	45	91	
Mean (StdDev)	2.2 (1.17)	2.5 (1.34)	2.1 (1.18)	1.9 (1.12)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	10	22	44	89	
LS Mean (StdErr) [2]	0.20 (0.371)	-0.32 (0.235)	-0.31 (0.150)	-0.76 (0.111)	
95% CI [2]	-0.56, 0.96	-0.80, 0.16	-0.61, -0.02	-0.98, -0.54	
Difference (95% CI) in CFB [2]		-0.52 (-1.35, 0.31)		-0.44 (-0.80, -0.09)	
p-value [3]		0.211		0.015	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	25	48	83	
Mean (StdDev)	2.2 (1.11)	2.2 (1.30)	2.1 (1.24)	1.8 (1.12)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	11	24	48	80	
LS Mean (StdErr) [2]	0.03 (0.368)	-0.42 (0.230)	-0.23 (0.148)	-0.82 (0.121)	
95% CI [2]	-0.72, 0.78	-0.89, 0.05	-0.52, 0.06	-1.06, -0.58	
Difference (95% CI) in CFB [2]		-0.45 (-1.27, 0.37)		-0.60 (-0.96, -0.23)	
p-value [3]		0.276		0.002	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	25	46	86	
Mean (StdDev)	2.0 (1.13)	2.1 (1.35)	2.0 (1.24)	1.8 (1.21)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	11	24	46	83	
LS Mean (StdErr) [2]	-0.17 (0.384)	-0.63 (0.240)	-0.29 (0.156)	-0.84 (0.123)	
95% CI [2]	-0.95, 0.62	-1.12, -0.14	-0.60, 0.02	-1.08, -0.60	
Difference (95% CI) in CFB [2]		-0.46 (-1.32, 0.40)		-0.55 (-0.93, -0.17)	
p-value [3]		0.281		0.005	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	11	24	47	87	
Mean (StdDev)	2.0 (1.18)	2.2 (1.27)	2.1 (1.19)	1.7 (1.24)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	10	23	47	84	
LS Mean (StdErr) [2]	0.20 (0.378)	-0.59 (0.231)	-0.21 (0.149)	-0.89 (0.116)	
95% CI [2]	-0.57, 0.97	-1.06, -0.11	-0.50, 0.09	-1.12, -0.66	
Difference (95% CI) in CFB [2]		-0.79 (-1.64, 0.06)		-0.68 (-1.04, -0.32)	
Hedges'G (95% CI) in CFB		-0.68 (-1.52, 0.07)		-0.65 (-1.03, -0.29)	
p-value [3]		0.069		<0.001	
					0.848

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	12	25	53	94	
Mean (StdDev)	2.5 (1.24)	2.3 (1.37)	2.0 (1.36)	2.1 (1.48)	
Median	2.5	3.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	52	94	
Mean (StdDev)	2.0 (1.22)	1.8 (1.22)	1.6 (1.43)	1.6 (1.45)	
Median	2.0	2.0	1.5	1.5	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	12	24	51	92	
LS Mean (StdErr) [2]	-0.06 (0.409)	-0.35 (0.259)	-0.44 (0.202)	-0.58 (0.160)	
95% CI [2]	-0.90, 0.77	-0.88, 0.17	-0.84, -0.04	-0.90, -0.27	
Difference (95% CI) in CFB [2]		-0.29 (-1.22, 0.64)		-0.14 (-0.64, 0.35)	
p-value [3]		0.533		0.566	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	24	50	85	
Mean (StdDev)	2.4 (1.26)	1.6 (1.41)	1.6 (1.29)	1.5 (1.38)	
Median	2.0	1.5	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	12	24	49	85	
LS Mean (StdErr) [2]	0.42 (0.409)	-0.49 (0.259)	-0.43 (0.215)	-0.62 (0.170)	
95% CI [2]	-0.41, 1.25	-1.02, 0.03	-0.86, -0.01	-0.96, -0.29	
Difference (95% CI) in CFB [2]		-0.91 (-1.84, 0.02)		-0.19 (-0.71, 0.33)	
p-value [3]		0.056		0.475	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	11	22	45	91	
Mean (StdDev)	1.8 (1.33)	1.8 (1.27)	1.9 (1.20)	1.5 (1.34)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	10	22	44	89	
LS Mean (StdErr) [2]	-0.03 (0.480)	-0.38 (0.303)	-0.17 (0.226)	-0.64 (0.167)	
95% CI [2]	-1.01, 0.95	-1.00, 0.24	-0.62, 0.28	-0.97, -0.31	
Difference (95% CI) in CFB [2]		-0.35 (-1.42, 0.73)		-0.47 (-1.01, 0.06)	
p-value [3]		0.515		0.083	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	25	47	84	
Mean (StdDev)	1.9 (1.24)	1.6 (1.32)	1.9 (1.22)	1.4 (1.30)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	11	24	47	81	
LS Mean (StdErr) [2]	-0.05 (0.389)	-0.42 (0.244)	-0.16 (0.219)	-0.91 (0.177)	
95% CI [2]	-0.84, 0.74	-0.92, 0.07	-0.60, 0.27	-1.26, -0.56	
Difference (95% CI) in CFB [2]		-0.37 (-1.24, 0.50)		-0.75 (-1.29, -0.21)	
p-value [3]		0.390		0.007	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	25	46	86	
Mean (StdDev)	1.8 (1.34)	1.7 (1.22)	2.0 (1.27)	1.4 (1.37)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	11	24	46	83	
LS Mean (StdErr) [2]	-0.18 (0.400)	-0.48 (0.250)	-0.07 (0.223)	-0.62 (0.176)	
95% CI [2]	-1.00, 0.63	-0.99, 0.03	-0.51, 0.37	-0.97, -0.27	
Difference (95% CI) in CFB [2]		-0.29 (-1.19, 0.60)		-0.55 (-1.10, -0.01)	
p-value [3]		0.507		0.047	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	11	24	47	87	
Mean (StdDev)	2.0 (1.10)	1.7 (1.37)	1.6 (1.34)	1.3 (1.30)	
Median	2.0	2.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	10	23	47	84	
LS Mean (StdErr) [2]	0.24 (0.377)	-0.40 (0.231)	-0.38 (0.218)	-0.77 (0.169)	
95% CI [2]	-0.53, 1.01	-0.87, 0.07	-0.81, 0.05	-1.10, -0.44	
Difference (95% CI) in CFB [2]		-0.64 (-1.49, 0.21)		-0.39 (-0.92, 0.14)	
Hedges'G (95% CI) in CFB		-0.55 (-1.37, 0.20)		-0.25 (-0.62, 0.10)	
p-value [3]		0.136		0.146	
					0.952

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	12	25	53	94	
Mean (StdDev)	2.8 (0.87)	2.4 (1.33)	2.4 (1.34)	2.7 (1.29)	
Median	3.0	3.0	3.0	3.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	52	94	
Mean (StdDev)	2.6 (0.96)	2.0 (1.19)	2.3 (1.30)	2.1 (1.34)	
Median	3.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	12	24	51	92	
LS Mean (StdErr) [2]	0.03 (0.328)	-0.38 (0.207)	-0.28 (0.169)	-0.64 (0.133)	
95% CI [2]	-0.63, 0.70	-0.80, 0.04	-0.62, 0.05	-0.90, -0.37	
Difference (95% CI) in CFB [2]		-0.42 (-1.16, 0.33)		-0.35 (-0.77, 0.06)	
p-value [3]		0.266		0.093	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	24	50	85	
Mean (StdDev)	2.4 (1.12)	1.9 (1.26)	2.3 (1.23)	1.9 (1.31)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	12	24	49	85	
LS Mean (StdErr) [2]	-0.14 (0.341)	-0.57 (0.216)	-0.22 (0.177)	-0.84 (0.140)	
95% CI [2]	-0.84, 0.55	-1.01, -0.13	-0.57, 0.13	-1.12, -0.56	
Difference (95% CI) in CFB [2]		-0.42 (-1.20, 0.35)		-0.62 (-1.05, -0.19)	
p-value [3]		0.276		0.005	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	11	22	45	91	
Mean (StdDev)	2.0 (1.18)	2.3 (1.52)	2.2 (1.35)	1.9 (1.30)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	10	22	44	89	
LS Mean (StdErr) [2]	-0.38 (0.522)	-0.40 (0.330)	-0.36 (0.181)	-0.83 (0.134)	
95% CI [2]	-1.45, 0.69	-1.08, 0.27	-0.72, -0.00	-1.10, -0.56	
Difference (95% CI) in CFB [2]		-0.02 (-1.19, 1.15)		-0.47 (-0.90, -0.04)	
p-value [3]		0.973		0.034	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	25	47	84	
Mean (StdDev)	2.0 (1.13)	1.9 (1.26)	2.2 (1.25)	1.7 (1.25)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	11	24	47	81	
LS Mean (StdErr) [2]	-0.61 (0.401)	-0.45 (0.251)	-0.25 (0.184)	-1.09 (0.148)	
95% CI [2]	-1.43, 0.20	-0.97, 0.06	-0.62, 0.11	-1.38, -0.79	
Difference (95% CI) in CFB [2]		0.16 (-0.74, 1.06)		-0.83 (-1.28, -0.38)	
p-value [3]		0.718		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	25	46	86	
Mean (StdDev)	2.3 (0.89)	2.0 (1.24)	2.4 (1.34)	1.7 (1.34)	
Median	2.0	2.0	2.5	1.5	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	11	24	46	83	
LS Mean (StdErr) [2]	-0.41 (0.414)	-0.52 (0.259)	-0.07 (0.187)	-0.96 (0.147)	
95% CI [2]	-1.25, 0.44	-1.04, 0.01	-0.44, 0.30	-1.25, -0.67	
Difference (95% CI) in CFB [2]		-0.11 (-1.04, 0.81)		-0.89 (-1.35, -0.43)	
p-value [3]		0.807		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	11	24	47	87	
Mean (StdDev)	2.0 (1.10)	1.8 (1.38)	2.2 (1.32)	1.8 (1.37)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	10	23	47	84	
LS Mean (StdErr) [2]	-0.43 (0.502)	-0.54 (0.307)	-0.29 (0.192)	-0.98 (0.149)	
95% CI [2]	-1.46, 0.59	-1.17, 0.09	-0.67, 0.09	-1.27, -0.68	
Difference (95% CI) in CFB [2]		-0.11 (-1.24, 1.02)		-0.69 (-1.16, -0.23)	
Hedges'G (95% CI) in CFB		-0.07 (-0.85, 0.70)		-0.51 (-0.89, -0.15)	
p-value [3]		0.849		0.004	
					0.238

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	12	25	53	94	
Mean (StdDev)	2.3 (1.50)	2.2 (1.07)	2.3 (1.35)	2.5 (1.09)	
Median	3.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	52	94	
Mean (StdDev)	2.4 (1.04)	1.7 (1.14)	2.0 (1.22)	1.9 (1.23)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	12	24	51	92	
LS Mean (StdErr) [2]	0.32 (0.499)	-0.35 (0.316)	-0.31 (0.149)	-0.66 (0.118)	
95% CI [2]	-0.70, 1.33	-0.99, 0.30	-0.60, -0.01	-0.89, -0.43	
Difference (95% CI) in CFB [2]		-0.66 (-1.80, 0.47)		-0.35 (-0.72, 0.01)	
p-value [3]		0.244		0.057	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	24	50	85	
Mean (StdDev)	1.8 (1.57)	2.0 (1.12)	2.0 (1.35)	1.7 (1.11)	
Median	1.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	12	24	49	85	
LS Mean (StdErr) [2]	-0.10 (0.329)	-0.07 (0.208)	-0.40 (0.160)	-0.86 (0.126)	
95% CI [2]	-0.77, 0.57	-0.50, 0.35	-0.72, -0.08	-1.11, -0.61	
Difference (95% CI) in CFB [2]		0.03 (-0.72, 0.78)		-0.46 (-0.85, -0.07)	
p-value [3]		0.934		0.020	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	11	22	45	91	
Mean (StdDev)	2.0 (1.48)	1.8 (1.18)	2.1 (1.32)	1.7 (1.23)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	10	22	44	89	
LS Mean (StdErr) [2]	-0.24 (0.344)	-0.34 (0.218)	-0.38 (0.200)	-0.87 (0.148)	
95% CI [2]	-0.94, 0.46	-0.78, 0.11	-0.77, 0.02	-1.16, -0.58	
Difference (95% CI) in CFB [2]		-0.10 (-0.87, 0.68)		-0.50 (-0.97, -0.02)	
p-value [3]		0.801		0.041	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	25	47	84	
Mean (StdDev)	1.8 (1.40)	1.5 (1.26)	2.1 (1.31)	1.7 (1.24)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	11	24	47	81	
LS Mean (StdErr) [2]	-0.16 (0.417)	-0.51 (0.261)	-0.15 (0.187)	-0.93 (0.151)	
95% CI [2]	-1.01, 0.69	-1.04, 0.03	-0.52, 0.22	-1.23, -0.63	
Difference (95% CI) in CFB [2]		-0.34 (-1.28, 0.59)		-0.78 (-1.24, -0.32)	
p-value [3]		0.458		0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	25	46	86	
Mean (StdDev)	1.8 (1.03)	1.8 (1.19)	2.3 (1.38)	1.5 (1.25)	
Median	1.5	2.0	2.5	1.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	11	24	46	83	
LS Mean (StdErr) [2]	-0.03 (0.402)	-0.20 (0.251)	0.03 (0.189)	-1.07 (0.149)	
95% CI [2]	-0.85, 0.78	-0.71, 0.31	-0.34, 0.40	-1.37, -0.78	
Difference (95% CI) in CFB [2]		-0.17 (-1.06, 0.73)		-1.10 (-1.56, -0.64)	
p-value [3]		0.711		<0.0001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	11	24	47	87	
Mean (StdDev)	1.5 (1.13)	1.9 (1.14)	2.1 (1.36)	1.6 (1.32)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	10	23	47	84	
LS Mean (StdErr) [2]	-0.20 (0.375)	-0.15 (0.230)	-0.17 (0.188)	-0.99 (0.146)	
95% CI [2]	-0.97, 0.57	-0.62, 0.32	-0.55, 0.20	-1.28, -0.70	
Difference (95% CI) in CFB [2]		0.05 (-0.79, 0.90)		-0.82 (-1.27, -0.36)	
Hedges'G (95% CI) in CFB		0.05 (-0.72, 0.82)		-0.62 (-1.00, -0.26)	
p-value [3]		0.898		<0.001	
					0.051

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	12	25	53	94	
Mean (StdDev)	1.6 (1.73)	1.8 (1.39)	1.8 (1.49)	1.9 (1.53)	
Median	1.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	52	94	
Mean (StdDev)	1.9 (1.32)	1.6 (1.08)	1.7 (1.56)	1.6 (1.55)	
Median	2.0	2.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	12	24	51	92	
LS Mean (StdErr) [2]	0.54 (0.316)	-0.23 (0.200)	-0.19 (0.159)	-0.43 (0.126)	
95% CI [2]	-0.10, 1.19	-0.64, 0.18	-0.50, 0.13	-0.68, -0.18	
Difference (95% CI) in CFB [2]		-0.77 (-1.49, -0.05)		-0.24 (-0.63, 0.15)	
p-value [3]		0.036		0.225	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	24	50	85	
Mean (StdDev)	1.4 (1.39)	1.5 (1.25)	1.6 (1.61)	1.3 (1.46)	
Median	1.0	1.5	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	12	24	49	85	
LS Mean (StdErr) [2]	-0.08 (0.282)	-0.22 (0.178)	-0.34 (0.171)	-0.61 (0.135)	
95% CI [2]	-0.65, 0.50	-0.59, 0.14	-0.68, -0.00	-0.88, -0.34	
Difference (95% CI) in CFB [2]		-0.15 (-0.79, 0.50)		-0.27 (-0.68, 0.15)	
p-value [3]		0.646		0.204	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	11	22	45	91	
Mean (StdDev)	1.2 (1.25)	1.7 (1.17)	1.7 (1.36)	1.3 (1.44)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	10	22	44	89	
LS Mean (StdErr) [2]	-0.05 (0.477)	-0.07 (0.301)	-0.34 (0.198)	-0.63 (0.147)	
95% CI [2]	-1.02, 0.93	-0.68, 0.55	-0.74, 0.05	-0.92, -0.34	
Difference (95% CI) in CFB [2]		-0.02 (-1.09, 1.05)		-0.29 (-0.76, 0.18)	
p-value [3]		0.971		0.231	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	25	47	83	
Mean (StdDev)	1.2 (1.19)	1.6 (1.26)	1.4 (1.47)	1.3 (1.40)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	11	24	47	80	
LS Mean (StdErr) [2]	0.03 (0.422)	-0.17 (0.264)	-0.39 (0.202)	-0.73 (0.163)	
95% CI [2]	-0.83, 0.89	-0.70, 0.37	-0.79, 0.01	-1.05, -0.40	
Difference (95% CI) in CFB [2]		-0.19 (-1.14, 0.75)		-0.34 (-0.84, 0.16)	
p-value [3]		0.682		0.176	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	25	46	86	
Mean (StdDev)	1.2 (1.27)	1.4 (1.22)	1.5 (1.43)	1.4 (1.52)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	11	24	46	83	
LS Mean (StdErr) [2]	-0.04 (0.470)	-0.31 (0.294)	-0.42 (0.217)	-0.67 (0.171)	
95% CI [2]	-1.00, 0.92	-0.91, 0.29	-0.85, 0.00	-1.01, -0.33	
Difference (95% CI) in CFB [2]		-0.27 (-1.32, 0.78)		-0.25 (-0.78, 0.28)	
p-value [3]		0.602		0.357	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	11	24	47	87	
Mean (StdDev)	1.3 (0.90)	1.5 (1.28)	1.5 (1.52)	1.3 (1.48)	
Median	1.0	2.0	1.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C7D1 CFB					
n	10	23	47	84	
LS Mean (StdErr) [2]	0.41 (0.482)	-0.09 (0.295)	-0.31 (0.202)	-0.65 (0.157)	
95% CI [2]	-0.58, 1.39	-0.70, 0.51	-0.71, 0.09	-0.96, -0.34	
Difference (95% CI) in CFB [2]		-0.50 (-1.59, 0.58)		-0.34 (-0.83, 0.15)	
Hedges'G (95% CI) in CFB		-0.34 (-1.14, 0.41)		-0.24 (-0.60, 0.12)	
p-value [3]		0.351		0.174	
					0.966

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	12	25	53	94	
Mean (StdDev)	2.0 (1.35)	2.3 (1.07)	2.2 (1.32)	2.4 (1.21)	
Median	2.0	2.0	2.0	2.5	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	52	94	
Mean (StdDev)	1.8 (1.14)	1.8 (1.09)	1.8 (1.28)	1.9 (1.19)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C2D1 CFB					
n	12	24	51	92	
LS Mean (StdErr) [2]	-0.15 (0.298)	-0.56 (0.189)	-0.43 (0.131)	-0.45 (0.103)	
95% CI [2]	-0.76, 0.46	-0.95, -0.18	-0.69, -0.17	-0.65, -0.24	
Difference (95% CI) in CFB [2]		-0.41 (-1.09, 0.27)		-0.02 (-0.34, 0.30)	
p-value [3]		0.226		0.913	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	24	50	85	
Mean (StdDev)	1.8 (1.34)	1.7 (1.12)	1.9 (1.29)	1.6 (1.33)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	12	24	49	85	
LS Mean (StdErr) [2]	-0.14 (0.306)	-0.68 (0.194)	-0.31 (0.155)	-0.77 (0.122)	
95% CI [2]	-0.76, 0.48	-1.08, -0.29	-0.61, 0.00	-1.02, -0.53	
Difference (95% CI) in CFB [2]		-0.54 (-1.24, 0.16)		-0.47 (-0.84, -0.09)	
p-value [3]		0.123		0.015	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	11	22	45	91	
Mean (StdDev)	1.6 (1.12)	1.7 (1.08)	1.9 (1.17)	1.6 (1.21)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C4D1 CFB					
n	10	22	44	89	
LS Mean (StdErr) [2]	0.19 (0.297)	-0.73 (0.188)	-0.44 (0.155)	-0.80 (0.115)	
95% CI [2]	-0.42, 0.80	-1.12, -0.35	-0.75, -0.13	-1.03, -0.58	
Difference (95% CI) in CFB [2]		-0.92 (-1.59, -0.26)		-0.36 (-0.73, 0.01)	
p-value [3]		0.008		0.054	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	25	47	84	
Mean (StdDev)	1.4 (1.08)	1.4 (1.16)	1.9 (1.24)	1.6 (1.26)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C5D1 CFB					
n	11	24	47	81	
LS Mean (StdErr) [2]	-0.75 (0.297)	-1.00 (0.186)	-0.33 (0.165)	-0.87 (0.133)	
95% CI [2]	-1.36, -0.15	-1.38, -0.62	-0.66, -0.01	-1.13, -0.61	
Difference (95% CI) in CFB [2]		-0.24 (-0.91, 0.42)		-0.53 (-0.94, -0.13)	
p-value [3]		0.461		0.010	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	25	46	86	
Mean (StdDev)	1.7 (1.23)	1.6 (1.22)	2.2 (1.20)	1.5 (1.39)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C6D1 CFB					
n	11	24	46	83	
LS Mean (StdErr) [2]	-0.24 (0.291)	-0.77 (0.182)	-0.07 (0.177)	-0.85 (0.139)	
95% CI [2]	-0.83, 0.36	-1.14, -0.40	-0.42, 0.28	-1.12, -0.57	
Difference (95% CI) in CFB [2]		-0.53 (-1.18, 0.12)		-0.78 (-1.21, -0.35)	
p-value [3]		0.107		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	11	24	47	87	
Mean (StdDev)	1.5 (1.04)	1.8 (1.32)	2.0 (1.44)	1.4 (1.34)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C7D1 CFB					
n	10	23	47	84	
LS Mean (StdErr) [2]	-0.08 (0.322)	-0.51 (0.197)	-0.30 (0.165)	-0.98 (0.128)	
95% CI [2]	-0.74, 0.58	-0.92, -0.11	-0.63, 0.02	-1.24, -0.73	
Difference (95% CI) in CFB [2]		-0.43 (-1.16, 0.29)		-0.68 (-1.08, -0.28)	
Hedges'G (95% CI) in CFB		-0.44 (-1.25, 0.31)		-0.58 (-0.96, -0.22)	
p-value [3]		0.232		0.001	
					0.565

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	12	25	53	94	
Mean (StdDev)	1.9 (1.24)	2.1 (1.30)	2.0 (1.44)	2.1 (1.30)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	52	94	
Mean (StdDev)	1.4 (1.19)	1.6 (1.19)	1.5 (1.23)	1.6 (1.31)	
Median	1.0	2.0	1.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C2D1 CFB					
n	12	24	51	92	
LS Mean (StdErr) [2]	-0.32 (0.358)	-0.43 (0.227)	-0.45 (0.146)	-0.51 (0.116)	
95% CI [2]	-1.05, 0.41	-0.89, 0.03	-0.73, -0.16	-0.74, -0.28	
Difference (95% CI) in CFB [2]		-0.11 (-0.93, 0.71)		-0.06 (-0.42, 0.29)	
p-value [3]		0.785		0.722	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	24	50	85	
Mean (StdDev)	1.4 (1.04)	1.6 (1.13)	1.7 (1.35)	1.4 (1.33)	
Median	1.0	1.5	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C3D1 CFB					
n	12	24	49	85	
LS Mean (StdErr) [2]	-0.35 (0.347)	-0.50 (0.220)	-0.30 (0.155)	-0.70 (0.122)	
95% CI [2]	-1.05, 0.36	-0.94, -0.05	-0.61, 0.01	-0.94, -0.46	
Difference (95% CI) in CFB [2]		-0.15 (-0.94, 0.64)		-0.40 (-0.77, -0.02)	
p-value [3]		0.707		0.038	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	11	22	45	91	
Mean (StdDev)	1.3 (0.90)	1.6 (1.22)	1.7 (1.21)	1.3 (1.27)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C4D1 CFB					
n	10	22	44	89	
LS Mean (StdErr) [2]	-0.46 (0.414)	-0.71 (0.262)	-0.47 (0.156)	-0.80 (0.115)	
95% CI [2]	-1.31, 0.39	-1.24, -0.17	-0.78, -0.16	-1.03, -0.57	
Difference (95% CI) in CFB [2]		-0.25 (-1.18, 0.68)		-0.33 (-0.70, 0.04)	
p-value [3]		0.586		0.080	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	25	47	84	
Mean (StdDev)	1.3 (1.06)	1.4 (1.08)	1.6 (1.36)	1.4 (1.27)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C5D1 CFB					
n	11	24	47	81	
LS Mean (StdErr) [2]	-0.42 (0.374)	-0.74 (0.234)	-0.30 (0.167)	-0.77 (0.135)	
95% CI [2]	-1.19, 0.34	-1.22, -0.26	-0.63, 0.03	-1.04, -0.50	
Difference (95% CI) in CFB [2]		-0.32 (-1.16, 0.52)		-0.47 (-0.88, -0.06)	
p-value [3]		0.443		0.025	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	25	46	86	
Mean (StdDev)	1.0 (1.04)	1.5 (1.12)	1.9 (1.26)	1.4 (1.42)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C6D1 CFB					
n	11	24	46	83	
LS Mean (StdErr) [2]	-0.68 (0.419)	-0.61 (0.262)	-0.12 (0.167)	-0.85 (0.131)	
95% CI [2]	-1.53, 0.17	-1.14, -0.07	-0.45, 0.21	-1.11, -0.59	
Difference (95% CI) in CFB [2]		0.07 (-0.86, 1.01)		-0.73 (-1.14, -0.32)	
p-value [3]		0.873		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	11	24	47	87	
Mean (StdDev)	1.4 (1.12)	1.5 (1.32)	1.6 (1.38)	1.2 (1.37)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C7D1 CFB					
n	10	23	47	84	
LS Mean (StdErr) [2]	-0.06 (0.433)	-0.55 (0.265)	-0.30 (0.165)	-0.83 (0.128)	
95% CI [2]	-0.94, 0.82	-1.09, -0.01	-0.63, 0.02	-1.09, -0.58	
Difference (95% CI) in CFB [2]		-0.49 (-1.46, 0.48)		-0.53 (-0.93, -0.13)	
Hedges'G (95% CI) in CFB		-0.37 (-1.17, 0.38)		-0.45 (-0.83, -0.10)	
p-value [3]		0.312		0.010	
					0.975

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	12	25	53	94	
Mean (StdDev)	2.7 (1.15)	2.8 (1.18)	3.1 (0.85)	2.9 (0.96)	
Median	2.5	3.0	3.0	3.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	52	94	
Mean (StdDev)	2.3 (1.25)	2.3 (0.90)	2.6 (1.04)	2.6 (1.04)	
Median	2.0	2.0	3.0	3.0	
Min, Max	0, 4	1, 4	0, 4	0, 4	
C2D1 CFB					
n	12	24	51	92	
LS Mean (StdErr) [2]	-0.63 (0.332)	-0.65 (0.210)	-0.49 (0.127)	-0.38 (0.100)	
95% CI [2]	-1.30, 0.05	-1.07, -0.22	-0.74, -0.24	-0.57, -0.18	
Difference (95% CI) in CFB [2]		-0.02 (-0.77, 0.74)		0.11 (-0.20, 0.42)	
p-value [3]		0.962		0.471	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	24	50	85	
Mean (StdDev)	2.5 (1.33)	2.4 (1.28)	2.6 (0.98)	2.2 (1.09)	
Median	3.0	3.0	3.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	12	24	49	85	
LS Mean (StdErr) [2]	-0.12 (0.267)	-0.38 (0.169)	-0.53 (0.147)	-0.79 (0.116)	
95% CI [2]	-0.67, 0.42	-0.72, -0.03	-0.82, -0.24	-1.02, -0.56	
Difference (95% CI) in CFB [2]		-0.26 (-0.87, 0.35)		-0.27 (-0.62, 0.09)	
p-value [3]		0.399		0.139	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	11	22	45	91	
Mean (StdDev)	2.4 (1.43)	2.4 (1.37)	2.4 (1.18)	2.3 (1.17)	
Median	3.0	2.5	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	10	22	44	89	
LS Mean (StdErr) [2]	-0.52 (0.383)	-0.46 (0.242)	-0.72 (0.157)	-0.62 (0.116)	
95% CI [2]	-1.31, 0.26	-0.96, 0.03	-1.03, -0.41	-0.85, -0.40	
Difference (95% CI) in CFB [2]		0.06 (-0.80, 0.92)		0.10 (-0.28, 0.47)	
p-value [3]		0.892		0.606	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	25	48	84	
Mean (StdDev)	2.5 (1.17)	1.9 (1.35)	2.6 (1.01)	2.1 (1.26)	
Median	2.5	2.0	3.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	11	24	48	81	
LS Mean (StdErr) [2]	-0.26 (0.385)	-0.99 (0.241)	-0.52 (0.166)	-0.91 (0.135)	
95% CI [2]	-1.04, 0.53	-1.48, -0.50	-0.85, -0.19	-1.18, -0.65	
Difference (95% CI) in CFB [2]		-0.73 (-1.59, 0.13)		-0.39 (-0.80, 0.02)	
p-value [3]		0.093		0.059	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	25	46	86	
Mean (StdDev)	2.4 (1.24)	2.5 (1.16)	2.6 (1.20)	2.1 (1.25)	
Median	2.0	3.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	11	24	46	83	
LS Mean (StdErr) [2]	-0.24 (0.425)	-0.40 (0.266)	-0.43 (0.172)	-0.84 (0.135)	
95% CI [2]	-1.10, 0.63	-0.94, 0.15	-0.77, -0.09	-1.11, -0.57	
Difference (95% CI) in CFB [2]		-0.16 (-1.11, 0.79)		-0.41 (-0.83, 0.01)	
p-value [3]		0.732		0.053	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	11	24	47	87	
Mean (StdDev)	2.3 (1.35)	2.3 (1.24)	2.6 (1.06)	2.1 (1.19)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	10	23	47	84	
LS Mean (StdErr) [2]	-0.11 (0.435)	-0.49 (0.266)	-0.48 (0.153)	-0.82 (0.119)	
95% CI [2]	-1.00, 0.78	-1.03, 0.06	-0.78, -0.18	-1.06, -0.59	
Difference (95% CI) in CFB [2]		-0.38 (-1.36, 0.60)		-0.34 (-0.71, 0.03)	
Hedges'G (95% CI) in CFB		-0.28 (-1.08, 0.47)		-0.32 (-0.68, 0.04)	
p-value [3]		0.438		0.071	
					0.994

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	12	25	53	94	
Mean (StdDev)	2.8 (1.29)	2.6 (1.00)	2.4 (1.50)	2.4 (1.28)	
Median	3.0	3.0	3.0	2.0	
Min, Max	0, 4	1, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	52	94	
Mean (StdDev)	2.3 (0.75)	2.2 (1.47)	2.2 (1.32)	1.9 (1.33)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	12	24	51	92	
LS Mean (StdErr) [2]	-0.71 (0.361)	-0.42 (0.228)	-0.21 (0.150)	-0.52 (0.119)	
95% CI [2]	-1.44, 0.02	-0.89, 0.04	-0.51, 0.08	-0.75, -0.29	
Difference (95% CI) in CFB [2]		0.29 (-0.53, 1.11)		-0.31 (-0.67, 0.06)	
p-value [3]		0.481		0.101	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	24	50	85	
Mean (StdDev)	2.2 (1.09)	2.1 (1.15)	2.3 (1.25)	1.7 (1.31)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	12	24	49	85	
LS Mean (StdErr) [2]	-0.83 (0.358)	-0.58 (0.227)	-0.14 (0.170)	-0.73 (0.135)	
95% CI [2]	-1.56, -0.10	-1.04, -0.12	-0.48, 0.19	-1.00, -0.46	
Difference (95% CI) in CFB [2]		0.25 (-0.57, 1.06)		-0.59 (-1.00, -0.18)	
p-value [3]		0.544		0.006	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	11	22	45	91	
Mean (StdDev)	2.2 (0.98)	2.4 (1.26)	2.0 (1.37)	1.7 (1.42)	
Median	2.0	3.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	10	22	44	89	
LS Mean (StdErr) [2]	-0.68 (0.364)	-0.22 (0.230)	-0.48 (0.166)	-0.90 (0.123)	
95% CI [2]	-1.42, 0.06	-0.69, 0.25	-0.81, -0.16	-1.14, -0.66	
Difference (95% CI) in CFB [2]		0.46 (-0.35, 1.28)		-0.41 (-0.81, -0.02)	
p-value [3]		0.256		0.040	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	25	48	84	
Mean (StdDev)	2.2 (1.03)	2.1 (1.41)	1.9 (1.56)	1.7 (1.47)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	11	24	48	81	
LS Mean (StdErr) [2]	-0.68 (0.335)	-0.48 (0.209)	-0.43 (0.171)	-0.89 (0.139)	
95% CI [2]	-1.36, -0.00	-0.90, -0.05	-0.76, -0.09	-1.17, -0.62	
Difference (95% CI) in CFB [2]		0.21 (-0.54, 0.95)		-0.46 (-0.89, -0.04)	
p-value [3]		0.581		0.031	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	25	46	86	
Mean (StdDev)	2.4 (0.67)	2.0 (1.41)	2.2 (1.42)	1.5 (1.37)	
Median	2.5	2.0	2.0	1.0	
Min, Max	1, 3	0, 4	0, 4	0, 4	
C6D1 CFB					
n	11	24	46	83	
LS Mean (StdErr) [2]	-0.54 (0.381)	-0.57 (0.239)	-0.17 (0.174)	-1.00 (0.137)	
95% CI [2]	-1.32, 0.24	-1.05, -0.08	-0.52, 0.17	-1.27, -0.73	
Difference (95% CI) in CFB [2]		-0.03 (-0.88, 0.82)		-0.83 (-1.25, -0.40)	
p-value [3]		0.947		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	11	24	47	87	
Mean (StdDev)	2.2 (0.98)	2.0 (1.33)	2.0 (1.52)	1.4 (1.42)	
Median	2.0	2.0	2.0	1.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	10	23	47	84	
LS Mean (StdErr) [2]	-0.49 (0.439)	-0.56 (0.269)	-0.41 (0.175)	-0.97 (0.136)	
95% CI [2]	-1.39, 0.40	-1.11, -0.01	-0.76, -0.07	-1.24, -0.71	
Difference (95% CI) in CFB [2]		-0.06 (-1.05, 0.92)		-0.56 (-0.99, -0.14)	
Hedges'G (95% CI) in CFB		-0.05 (-0.82, 0.72)		-0.46 (-0.83, -0.10)	
p-value [3]		0.896		0.010	
					0.357

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	12	25	53	94	
Mean (StdDev)	2.8 (1.11)	3.1 (0.73)	2.8 (1.15)	3.0 (1.02)	
Median	3.0	3.0	3.0	3.0	
Min, Max	0, 4	2, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	52	94	
Mean (StdDev)	2.1 (1.04)	2.4 (1.32)	2.3 (1.16)	2.3 (1.22)	
Median	2.0	3.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	12	24	51	92	
LS Mean (StdErr) [2]	-0.89 (0.340)	-0.71 (0.216)	-0.53 (0.140)	-0.73 (0.111)	
95% CI [2]	-1.59, -0.20	-1.15, -0.27	-0.81, -0.25	-0.95, -0.51	
Difference (95% CI) in CFB [2]		0.18 (-0.59, 0.96)		-0.20 (-0.54, 0.15)	
p-value [3]		0.633		0.256	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	24	50	85	
Mean (StdDev)	2.5 (1.51)	2.3 (1.05)	2.3 (1.14)	2.0 (1.26)	
Median	3.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	12	24	49	85	
LS Mean (StdErr) [2]	-0.47 (0.343)	-0.87 (0.217)	-0.47 (0.161)	-1.00 (0.127)	
95% CI [2]	-1.17, 0.23	-1.32, -0.43	-0.79, -0.15	-1.25, -0.75	
Difference (95% CI) in CFB [2]		-0.40 (-1.18, 0.38)		-0.53 (-0.92, -0.14)	
p-value [3]		0.301		0.008	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	11	22	45	91	
Mean (StdDev)	2.3 (1.19)	2.5 (0.86)	2.5 (1.18)	2.0 (1.30)	
Median	3.0	2.0	2.0	2.0	
Min, Max	0, 4	1, 4	0, 4	0, 4	
C4D1 CFB					
n	10	22	44	89	
LS Mean (StdErr) [2]	-0.48 (0.264)	-0.81 (0.167)	-0.38 (0.171)	-1.03 (0.127)	
95% CI [2]	-1.02, 0.06	-1.15, -0.47	-0.72, -0.04	-1.28, -0.78	
Difference (95% CI) in CFB [2]		-0.33 (-0.92, 0.26)		-0.65 (-1.05, -0.24)	
p-value [3]		0.268		0.002	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	25	48	83	
Mean (StdDev)	1.9 (1.08)	2.2 (1.28)	2.4 (1.20)	2.0 (1.18)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	11	24	48	80	
LS Mean (StdErr) [2]	-0.74 (0.328)	-0.89 (0.205)	-0.38 (0.161)	-1.04 (0.131)	
95% CI [2]	-1.41, -0.07	-1.30, -0.47	-0.70, -0.07	-1.30, -0.78	
Difference (95% CI) in CFB [2]		-0.14 (-0.88, 0.59)		-0.66 (-1.06, -0.26)	
p-value [3]		0.694		0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	25	46	86	
Mean (StdDev)	1.8 (0.87)	2.0 (1.37)	2.7 (1.16)	1.9 (1.30)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C6D1 CFB					
n	11	24	46	83	
LS Mean (StdErr) [2]	-0.92 (0.341)	-1.13 (0.213)	-0.13 (0.171)	-1.04 (0.135)	
95% CI [2]	-1.61, -0.22	-1.56, -0.69	-0.46, 0.21	-1.31, -0.77	
Difference (95% CI) in CFB [2]		-0.21 (-0.97, 0.55)		-0.91 (-1.33, -0.49)	
p-value [3]		0.574		<0.0001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	11	24	47	87	
Mean (StdDev)	2.3 (1.35)	2.2 (1.34)	2.2 (1.34)	1.8 (1.33)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	10	23	47	84	
LS Mean (StdErr) [2]	-0.28 (0.371)	-0.86 (0.227)	-0.50 (0.168)	-1.06 (0.130)	
95% CI [2]	-1.04, 0.47	-1.33, -0.40	-0.83, -0.16	-1.32, -0.80	
Difference (95% CI) in CFB [2]		-0.58 (-1.42, 0.26)		-0.57 (-0.97, -0.16)	
Hedges'G (95% CI) in CFB		-0.51 (-1.33, 0.24)		-0.48 (-0.85, -0.12)	
p-value [3]		0.167		0.007	
					0.917

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	12	25	53	94	
Mean (StdDev)	3.1 (0.90)	3.2 (0.82)	3.1 (0.94)	3.1 (0.97)	
Median	3.0	3.0	3.0	3.0	
Min, Max	2, 4	2, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	52	94	
Mean (StdDev)	2.3 (0.95)	2.6 (0.82)	2.7 (1.00)	2.3 (1.13)	
Median	2.0	2.0	3.0	2.0	
Min, Max	1, 4	1, 4	0, 4	0, 4	
C2D1 CFB					
n	12	24	51	92	
LS Mean (StdErr) [2]	-0.75 (0.259)	-0.58 (0.164)	-0.40 (0.131)	-0.87 (0.104)	
95% CI [2]	-1.28, -0.22	-0.92, -0.25	-0.66, -0.14	-1.07, -0.66	
Difference (95% CI) in CFB [2]		0.17 (-0.42, 0.76)		-0.46 (-0.78, -0.14)	
p-value [3]		0.569		0.005	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	24	50	85	
Mean (StdDev)	2.4 (1.33)	2.4 (0.97)	2.5 (1.03)	2.0 (1.21)	
Median	2.0	2.5	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	12	24	49	85	
LS Mean (StdErr) [2]	-0.66 (0.336)	-0.83 (0.213)	-0.60 (0.152)	-1.10 (0.120)	
95% CI [2]	-1.34, 0.03	-1.26, -0.40	-0.90, -0.30	-1.33, -0.86	
Difference (95% CI) in CFB [2]		-0.17 (-0.94, 0.59)		-0.50 (-0.87, -0.13)	
p-value [3]		0.647		0.008	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	11	22	45	91	
Mean (StdDev)	2.2 (1.17)	2.5 (0.91)	2.5 (1.14)	2.0 (1.17)	
Median	2.0	2.5	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	10	22	44	89	
LS Mean (StdErr) [2]	-1.07 (0.359)	-0.89 (0.227)	-0.63 (0.150)	-1.21 (0.111)	
95% CI [2]	-1.80, -0.33	-1.36, -0.43	-0.93, -0.34	-1.42, -0.99	
Difference (95% CI) in CFB [2]		0.17 (-0.63, 0.98)		-0.57 (-0.93, -0.22)	
p-value [3]		0.663		0.002	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	25	48	84	
Mean (StdDev)	1.9 (1.08)	2.4 (1.08)	2.5 (1.30)	2.1 (1.21)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	11	24	48	81	
LS Mean (StdErr) [2]	-1.08 (0.361)	-0.75 (0.226)	-0.46 (0.165)	-1.09 (0.134)	
95% CI [2]	-1.82, -0.35	-1.21, -0.29	-0.79, -0.14	-1.36, -0.83	
Difference (95% CI) in CFB [2]		0.34 (-0.47, 1.14)		-0.63 (-1.03, -0.22)	
p-value [3]		0.401		0.003	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	25	46	86	
Mean (StdDev)	1.9 (0.90)	2.3 (1.25)	2.8 (1.15)	1.9 (1.28)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C6D1 CFB					
n	11	24	46	83	
LS Mean (StdErr) [2]	-1.22 (0.359)	-0.93 (0.224)	-0.30 (0.174)	-1.19 (0.137)	
95% CI [2]	-1.95, -0.49	-1.38, -0.47	-0.64, 0.05	-1.46, -0.92	
Difference (95% CI) in CFB [2]		0.29 (-0.51, 1.09)		-0.89 (-1.32, -0.47)	
p-value [3]		0.467		<0.0001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	11	24	47	87	
Mean (StdDev)	2.0 (1.34)	2.4 (1.38)	2.5 (1.32)	1.9 (1.23)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	10	23	47	84	
LS Mean (StdErr) [2]	-0.82 (0.470)	-0.75 (0.288)	-0.54 (0.164)	-1.25 (0.127)	
95% CI [2]	-1.78, 0.14	-1.34, -0.17	-0.87, -0.22	-1.50, -1.00	
Difference (95% CI) in CFB [2]		0.07 (-0.99, 1.13)		-0.70 (-1.10, -0.31)	
Hedges'G (95% CI) in CFB		0.05 (-0.72, 0.82)		-0.61 (-0.98, -0.25)	
p-value [3]		0.893		<0.001	
					0.112

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	12	25	53	94	
Mean (StdDev)	2.3 (1.23)	2.0 (1.49)	2.3 (1.50)	1.9 (1.49)	
Median	2.5	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	52	94	
Mean (StdDev)	2.2 (1.46)	2.2 (1.40)	1.9 (1.43)	1.3 (1.38)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	12	24	51	92	
LS Mean (StdErr) [2]	0.07 (0.423)	0.23 (0.268)	-0.33 (0.161)	-0.50 (0.127)	
95% CI [2]	-0.79, 0.93	-0.32, 0.77	-0.65, -0.02	-0.75, -0.24	
Difference (95% CI) in CFB [2]		0.16 (-0.81, 1.12)		-0.16 (-0.56, 0.23)	
p-value [3]		0.741		0.417	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	24	50	85	
Mean (StdDev)	1.8 (1.42)	2.0 (1.22)	2.1 (1.38)	1.2 (1.43)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	12	24	49	85	
LS Mean (StdErr) [2]	-0.38 (0.437)	-0.01 (0.277)	-0.14 (0.183)	-0.55 (0.145)	
95% CI [2]	-1.27, 0.51	-0.57, 0.56	-0.50, 0.22	-0.84, -0.27	
Difference (95% CI) in CFB [2]		0.37 (-0.62, 1.37)		-0.41 (-0.86, 0.03)	
p-value [3]		0.450		0.066	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	11	22	45	91	
Mean (StdDev)	1.9 (1.14)	2.1 (1.34)	1.9 (1.32)	1.4 (1.42)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C4D1 CFB					
n	10	22	44	89	
LS Mean (StdErr) [2]	-0.21 (0.469)	0.04 (0.297)	-0.41 (0.174)	-0.47 (0.129)	
95% CI [2]	-1.17, 0.75	-0.57, 0.65	-0.75, -0.06	-0.72, -0.21	
Difference (95% CI) in CFB [2]		0.25 (-0.80, 1.30)		-0.06 (-0.47, 0.36)	
p-value [3]		0.630		0.788	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	25	48	84	
Mean (StdDev)	1.7 (1.15)	2.0 (1.29)	1.9 (1.41)	1.3 (1.40)	
Median	1.5	2.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C5D1 CFB					
n	11	24	48	81	
LS Mean (StdErr) [2]	-0.53 (0.387)	0.17 (0.242)	-0.34 (0.196)	-0.64 (0.160)	
95% CI [2]	-1.32, 0.26	-0.32, 0.66	-0.73, 0.05	-0.96, -0.33	
Difference (95% CI) in CFB [2]		0.70 (-0.17, 1.56)		-0.30 (-0.79, 0.18)	
p-value [3]		0.111		0.215	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	25	46	86	
Mean (StdDev)	1.3 (1.30)	1.8 (1.30)	2.1 (1.47)	1.3 (1.37)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	11	24	46	83	
LS Mean (StdErr) [2]	-0.89 (0.443)	-0.04 (0.277)	-0.21 (0.200)	-0.60 (0.157)	
95% CI [2]	-1.79, 0.01	-0.60, 0.53	-0.61, 0.18	-0.91, -0.29	
Difference (95% CI) in CFB [2]		0.85 (-0.14, 1.84)		-0.39 (-0.88, 0.10)	
p-value [3]		0.090		0.115	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	11	24	47	87	
Mean (StdDev)	1.9 (1.38)	2.0 (1.43)	2.0 (1.53)	1.1 (1.27)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	10	23	47	84	
LS Mean (StdErr) [2]	-0.08 (0.494)	0.09 (0.302)	-0.22 (0.194)	-0.66 (0.151)	
95% CI [2]	-1.09, 0.93	-0.53, 0.71	-0.60, 0.17	-0.96, -0.36	
Difference (95% CI) in CFB [2]		0.17 (-0.94, 1.28)		-0.44 (-0.91, 0.03)	
Hedges'G (95% CI) in CFB		0.11 (-0.65, 0.89)		-0.32 (-0.69, 0.03)	
p-value [3]		0.759		0.065	
					0.305

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	12	25	53	94	
Mean (StdDev)	2.3 (1.42)	2.2 (1.49)	1.6 (1.18)	1.7 (1.26)	
Median	2.0	3.0	1.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	52	94	
Mean (StdDev)	1.9 (0.86)	1.6 (1.41)	1.4 (1.12)	1.3 (1.22)	
Median	2.0	1.0	1.0	1.0	
Min, Max	1, 3	0, 4	0, 4	0, 4	
C2D1 CFB					
n	12	24	51	92	
LS Mean (StdErr) [2]	-0.41 (0.274)	-0.62 (0.173)	-0.20 (0.123)	-0.30 (0.097)	
95% CI [2]	-0.97, 0.14	-0.98, -0.27	-0.45, 0.04	-0.49, -0.11	
Difference (95% CI) in CFB [2]		-0.21 (-0.83, 0.41)		-0.10 (-0.40, 0.20)	
p-value [3]		0.498		0.517	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	24	50	85	
Mean (StdDev)	1.5 (1.05)	1.3 (1.31)	1.6 (1.20)	1.1 (1.19)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	12	24	49	85	
LS Mean (StdErr) [2]	-0.77 (0.406)	-0.77 (0.257)	-0.01 (0.158)	-0.52 (0.125)	
95% CI [2]	-1.60, 0.05	-1.30, -0.25	-0.32, 0.30	-0.76, -0.27	
Difference (95% CI) in CFB [2]		-0.00 (-0.93, 0.92)		-0.50 (-0.88, -0.12)	
p-value [3]		0.998		0.010	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	11	22	45	91	
Mean (StdDev)	1.6 (1.03)	1.2 (1.19)	1.6 (1.20)	1.1 (1.20)	
Median	2.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	10	22	44	89	
LS Mean (StdErr) [2]	-0.44 (0.365)	-0.88 (0.231)	-0.09 (0.175)	-0.57 (0.130)	
95% CI [2]	-1.19, 0.31	-1.35, -0.41	-0.43, 0.26	-0.83, -0.31	
Difference (95% CI) in CFB [2]		-0.44 (-1.26, 0.38)		-0.48 (-0.90, -0.07)	
p-value [3]		0.278		0.023	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	25	48	84	
Mean (StdDev)	1.4 (0.79)	1.2 (1.30)	1.5 (1.22)	1.0 (1.19)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C5D1 CFB					
n	11	24	48	81	
LS Mean (StdErr) [2]	-0.85 (0.361)	-0.85 (0.226)	-0.11 (0.156)	-0.67 (0.127)	
95% CI [2]	-1.58, -0.11	-1.31, -0.39	-0.42, 0.20	-0.92, -0.42	
Difference (95% CI) in CFB [2]		-0.00 (-0.81, 0.81)		-0.56 (-0.94, -0.17)	
p-value [3]		0.998		0.005	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	25	46	86	
Mean (StdDev)	1.5 (1.00)	1.3 (1.35)	1.6 (1.22)	1.1 (1.15)	
Median	1.5	1.0	1.5	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C6D1 CFB					
n	11	24	46	83	
LS Mean (StdErr) [2]	-0.68 (0.397)	-0.73 (0.249)	-0.07 (0.154)	-0.60 (0.122)	
95% CI [2]	-1.49, 0.13	-1.24, -0.23	-0.37, 0.24	-0.85, -0.36	
Difference (95% CI) in CFB [2]		-0.06 (-0.95, 0.83)		-0.54 (-0.91, -0.16)	
p-value [3]		0.897		0.006	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	11	24	47	87	
Mean (StdDev)	1.3 (0.90)	1.3 (1.33)	1.3 (1.17)	0.9 (1.11)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C7D1 CFB					
n	10	23	47	84	
LS Mean (StdErr) [2]	-0.45 (0.457)	-0.56 (0.280)	-0.26 (0.141)	-0.62 (0.109)	
95% CI [2]	-1.38, 0.49	-1.13, 0.01	-0.54, 0.02	-0.84, -0.41	
Difference (95% CI) in CFB [2]		-0.11 (-1.14, 0.92)		-0.36 (-0.70, -0.02)	
Hedges'G (95% CI) in CFB		-0.08 (-0.86, 0.69)		-0.36 (-0.73, -0.01)	
p-value [3]		0.824		0.038	
					0.354

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	12	25	53	94	
Mean (StdDev)	1.5 (1.24)	1.4 (1.50)	1.2 (1.29)	1.5 (1.47)	
Median	1.5	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	52	94	
Mean (StdDev)	1.6 (1.39)	1.3 (1.44)	1.1 (1.32)	1.2 (1.36)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	12	24	51	92	
LS Mean (StdErr) [2]	-0.12 (0.382)	-0.05 (0.242)	-0.01 (0.136)	-0.17 (0.108)	
95% CI [2]	-0.90, 0.66	-0.54, 0.44	-0.27, 0.26	-0.38, 0.05	
Difference (95% CI) in CFB [2]		0.07 (-0.81, 0.94)		-0.16 (-0.49, 0.17)	
p-value [3]		0.879		0.345	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	24	50	85	
Mean (StdDev)	1.4 (1.19)	1.0 (1.18)	1.0 (1.19)	1.0 (1.27)	
Median	1.0	1.0	1.0	0.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	12	24	49	85	
LS Mean (StdErr) [2]	0.07 (0.426)	-0.22 (0.270)	-0.18 (0.158)	-0.42 (0.125)	
95% CI [2]	-0.79, 0.94	-0.77, 0.33	-0.49, 0.14	-0.67, -0.17	
Difference (95% CI) in CFB [2]		-0.29 (-1.26, 0.68)		-0.24 (-0.63, 0.14)	
p-value [3]		0.542		0.210	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	11	22	45	91	
Mean (StdDev)	1.5 (1.29)	0.8 (0.97)	1.4 (1.28)	1.1 (1.29)	
Median	1.0	0.0	1.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C4D1 CFB					
n	10	22	44	89	
LS Mean (StdErr) [2]	-0.15 (0.343)	-0.62 (0.217)	0.10 (0.180)	-0.36 (0.133)	
95% CI [2]	-0.86, 0.55	-1.06, -0.17	-0.26, 0.45	-0.62, -0.09	
Difference (95% CI) in CFB [2]		-0.46 (-1.23, 0.31)		-0.45 (-0.88, -0.02)	
p-value [3]		0.229		0.038	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	25	48	84	
Mean (StdDev)	1.3 (1.30)	0.9 (1.15)	1.2 (1.25)	0.9 (1.26)	
Median	1.0	0.0	1.0	0.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C5D1 CFB					
n	11	24	48	81	
LS Mean (StdErr) [2]	-0.36 (0.366)	-0.46 (0.229)	0.02 (0.157)	-0.57 (0.127)	
95% CI [2]	-1.11, 0.38	-0.92, 0.01	-0.29, 0.33	-0.82, -0.31	
Difference (95% CI) in CFB [2]		-0.10 (-0.92, 0.72)		-0.58 (-0.97, -0.20)	
p-value [3]		0.813		0.003	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	25	46	86	
Mean (StdDev)	1.3 (1.23)	0.8 (1.08)	1.2 (1.26)	1.0 (1.24)	
Median	1.0	0.0	1.0	0.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C6D1 CFB					
n	11	24	46	83	
LS Mean (StdErr) [2]	-0.28 (0.354)	-0.58 (0.221)	0.01 (0.169)	-0.51 (0.133)	
95% CI [2]	-1.00, 0.44	-1.04, -0.13	-0.33, 0.34	-0.77, -0.24	
Difference (95% CI) in CFB [2]		-0.31 (-1.10, 0.48)		-0.51 (-0.92, -0.10)	
p-value [3]		0.433		0.015	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	11	24	47	87	
Mean (StdDev)	1.1 (0.94)	0.9 (1.33)	1.2 (1.26)	0.9 (1.24)	
Median	1.0	0.0	1.0	0.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C7D1 CFB					
n	10	23	47	84	
LS Mean (StdErr) [2]	-0.10 (0.399)	-0.27 (0.244)	0.00 (0.158)	-0.48 (0.123)	
95% CI [2]	-0.91, 0.72	-0.77, 0.23	-0.31, 0.32	-0.72, -0.23	
Difference (95% CI) in CFB [2]		-0.17 (-1.07, 0.73)		-0.48 (-0.86, -0.10)	
Hedges'G (95% CI) in CFB		-0.14 (-0.92, 0.62)		-0.43 (-0.80, -0.07)	
p-value [3]		0.697		0.014	
					0.441

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	12	25	53	94	
Mean (StdDev)	2.1 (0.79)	2.3 (1.37)	2.0 (1.18)	1.9 (1.27)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 3	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	52	94	
Mean (StdDev)	1.1 (1.04)	1.7 (1.24)	1.6 (1.28)	1.4 (1.26)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C2D1 CFB					
n	12	24	51	92	
LS Mean (StdErr) [2]	-0.97 (0.298)	-0.60 (0.189)	-0.32 (0.153)	-0.51 (0.121)	
95% CI [2]	-1.58, -0.36	-0.98, -0.22	-0.62, -0.02	-0.75, -0.27	
Difference (95% CI) in CFB [2]		0.37 (-0.31, 1.05)		-0.19 (-0.56, 0.18)	
p-value [3]		0.275		0.315	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	24	50	85	
Mean (StdDev)	1.5 (0.88)	1.5 (1.06)	1.6 (1.18)	1.3 (1.15)	
Median	1.0	1.5	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C3D1 CFB					
n	12	24	49	85	
LS Mean (StdErr) [2]	-0.48 (0.255)	-0.75 (0.161)	-0.38 (0.155)	-0.55 (0.123)	
95% CI [2]	-1.00, 0.03	-1.07, -0.42	-0.69, -0.07	-0.79, -0.30	
Difference (95% CI) in CFB [2]		-0.26 (-0.84, 0.32)		-0.17 (-0.54, 0.21)	
p-value [3]		0.367		0.378	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	11	22	45	91	
Mean (StdDev)	1.4 (1.12)	1.8 (1.14)	1.6 (1.29)	1.3 (1.22)	
Median	1.0	2.0	1.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C4D1 CFB					
n	10	22	44	89	
LS Mean (StdErr) [2]	-0.64 (0.435)	-0.70 (0.275)	-0.33 (0.171)	-0.68 (0.126)	
95% CI [2]	-1.53, 0.25	-1.26, -0.14	-0.66, 0.01	-0.93, -0.43	
Difference (95% CI) in CFB [2]		-0.06 (-1.03, 0.92)		-0.35 (-0.76, 0.05)	
p-value [3]		0.905		0.088	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	25	48	84	
Mean (StdDev)	1.3 (0.89)	1.6 (0.99)	1.5 (1.40)	1.0 (1.21)	
Median	1.0	2.0	1.0	1.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C5D1 CFB					
n	11	24	48	81	
LS Mean (StdErr) [2]	-0.64 (0.342)	-0.67 (0.214)	-0.39 (0.166)	-0.89 (0.135)	
95% CI [2]	-1.34, 0.06	-1.10, -0.23	-0.71, -0.06	-1.16, -0.62	
Difference (95% CI) in CFB [2]		-0.03 (-0.80, 0.74)		-0.50 (-0.91, -0.09)	
p-value [3]		0.939		0.016	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	25	46	86	
Mean (StdDev)	1.1 (1.08)	1.3 (1.07)	1.7 (1.31)	1.0 (1.14)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C6D1 CFB					
n	11	24	46	83	
LS Mean (StdErr) [2]	-0.85 (0.414)	-0.97 (0.259)	-0.20 (0.168)	-1.08 (0.133)	
95% CI [2]	-1.69, -0.01	-1.50, -0.44	-0.53, 0.14	-1.35, -0.82	
Difference (95% CI) in CFB [2]		-0.12 (-1.05, 0.81)		-0.89 (-1.30, -0.48)	
p-value [3]		0.793		<0.0001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	11	24	47	87	
Mean (StdDev)	1.2 (0.98)	1.8 (1.26)	1.7 (1.42)	1.0 (1.20)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C7D1 CFB					
n	10	23	47	84	
LS Mean (StdErr) [2]	-0.64 (0.493)	-0.50 (0.302)	-0.25 (0.185)	-0.90 (0.144)	
95% CI [2]	-1.65, 0.36	-1.12, 0.12	-0.62, 0.12	-1.18, -0.61	
Difference (95% CI) in CFB [2]		0.14 (-0.97, 1.25)		-0.64 (-1.09, -0.20)	
Hedges'G (95% CI) in CFB		0.09 (-0.67, 0.87)		-0.49 (-0.87, -0.14)	
p-value [3]		0.794		0.005	
					0.147

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	12	25	53	94	
Mean (StdDev)	2.0 (1.04)	2.6 (1.33)	2.4 (0.99)	2.3 (1.16)	
Median	2.0	3.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	52	94	
Mean (StdDev)	1.5 (0.97)	2.0 (1.29)	1.8 (1.17)	1.6 (1.29)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C2D1 CFB					
n	12	24	51	92	
LS Mean (StdErr) [2]	-0.32 (0.274)	-0.54 (0.174)	-0.58 (0.154)	-0.69 (0.122)	
95% CI [2]	-0.88, 0.24	-0.89, -0.18	-0.88, -0.27	-0.93, -0.44	
Difference (95% CI) in CFB [2]		-0.22 (-0.84, 0.41)		-0.11 (-0.49, 0.27)	
p-value [3]		0.484		0.569	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	24	50	85	
Mean (StdDev)	1.5 (1.13)	1.8 (1.14)	1.9 (1.10)	1.3 (1.11)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	12	24	49	85	
LS Mean (StdErr) [2]	-0.52 (0.341)	-0.80 (0.216)	-0.46 (0.162)	-0.88 (0.128)	
95% CI [2]	-1.22, 0.17	-1.24, -0.36	-0.78, -0.14	-1.13, -0.63	
Difference (95% CI) in CFB [2]		-0.27 (-1.05, 0.50)		-0.42 (-0.81, -0.03)	
p-value [3]		0.477		0.036	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	11	22	45	90	
Mean (StdDev)	1.1 (0.83)	1.9 (1.28)	2.0 (1.13)	1.4 (1.24)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C4D1 CFB					
n	10	22	44	88	
LS Mean (StdErr) [2]	-0.95 (0.406)	-0.93 (0.257)	-0.47 (0.172)	-0.95 (0.128)	
95% CI [2]	-1.78, -0.12	-1.46, -0.41	-0.81, -0.12	-1.20, -0.69	
Difference (95% CI) in CFB [2]		0.02 (-0.89, 0.93)		-0.48 (-0.89, -0.07)	
p-value [3]		0.966		0.022	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	25	48	84	
Mean (StdDev)	1.2 (0.72)	1.6 (1.15)	1.8 (1.42)	1.3 (1.25)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	
C5D1 CFB					
n	11	24	48	81	
LS Mean (StdErr) [2]	-0.66 (0.363)	-0.89 (0.227)	-0.65 (0.181)	-1.05 (0.147)	
95% CI [2]	-1.40, 0.08	-1.35, -0.43	-1.01, -0.29	-1.34, -0.76	
Difference (95% CI) in CFB [2]		-0.23 (-1.04, 0.58)		-0.40 (-0.85, 0.05)	
p-value [3]		0.567		0.079	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	25	46	86	
Mean (StdDev)	1.1 (1.08)	1.6 (1.25)	1.9 (1.24)	1.2 (1.25)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C6D1 CFB					
n	11	24	46	83	
LS Mean (StdErr) [2]	-1.03 (0.456)	-0.96 (0.286)	-0.51 (0.173)	-1.13 (0.137)	
95% CI [2]	-1.96, -0.10	-1.54, -0.38	-0.85, -0.17	-1.40, -0.86	
Difference (95% CI) in CFB [2]		0.07 (-0.95, 1.09)		-0.62 (-1.04, -0.19)	
p-value [3]		0.895		0.005	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	11	24	47	87	
Mean (StdDev)	1.1 (0.83)	1.8 (1.35)	1.7 (1.29)	1.2 (1.21)	
Median	1.0	1.5	2.0	1.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	
C7D1 CFB					
n	10	23	47	84	
LS Mean (StdErr) [2]	-0.52 (0.384)	-0.67 (0.235)	-0.72 (0.184)	-1.01 (0.143)	
95% CI [2]	-1.31, 0.26	-1.15, -0.19	-1.08, -0.36	-1.30, -0.73	
Difference (95% CI) in CFB [2]		-0.14 (-1.01, 0.72)		-0.29 (-0.74, 0.15)	
Hedges'G (95% CI) in CFB		-0.12 (-0.90, 0.64)		-0.23 (-0.59, 0.13)	
p-value [3]		0.738		0.196	
					0.797

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	12	25	53	94	
Mean (StdDev)	2.4 (1.31)	2.9 (1.13)	2.7 (1.11)	2.7 (1.08)	
Median	2.5	3.0	3.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	52	94	
Mean (StdDev)	1.9 (1.26)	2.4 (0.99)	2.4 (1.09)	2.2 (1.24)	
Median	2.0	3.0	2.0	2.0	
Min, Max	0, 4	1, 4	0, 4	0, 4	
C2D1 CFB					
n	12	24	51	92	
LS Mean (StdErr) [2]	-0.39 (0.425)	-0.55 (0.269)	-0.24 (0.122)	-0.50 (0.097)	
95% CI [2]	-1.25, 0.48	-1.10, -0.00	-0.48, 0.01	-0.69, -0.31	
Difference (95% CI) in CFB [2]		-0.16 (-1.13, 0.81)		-0.26 (-0.56, 0.03)	
p-value [3]		0.737		0.083	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	24	50	86	
Mean (StdDev)	2.1 (1.61)	2.3 (1.22)	2.3 (1.05)	2.1 (1.13)	
Median	1.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	12	24	49	85	
LS Mean (StdErr) [2]	-0.35 (0.425)	-0.61 (0.269)	-0.49 (0.134)	-0.66 (0.106)	
95% CI [2]	-1.22, 0.52	-1.15, -0.06	-0.75, -0.22	-0.87, -0.45	
Difference (95% CI) in CFB [2]		-0.25 (-1.22, 0.72)		-0.17 (-0.50, 0.15)	
p-value [3]		0.597		0.299	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	11	22	45	91	
Mean (StdDev)	1.7 (1.35)	2.5 (0.91)	2.5 (1.04)	1.9 (1.19)	
Median	1.0	2.0	2.0	2.0	
Min, Max	0, 4	1, 4	0, 4	0, 4	
C4D1 CFB					
n	10	22	44	89	
LS Mean (StdErr) [2]	-0.78 (0.371)	-0.49 (0.234)	-0.18 (0.171)	-0.75 (0.126)	
95% CI [2]	-1.54, -0.02	-0.97, -0.01	-0.52, 0.15	-1.00, -0.50	
Difference (95% CI) in CFB [2]		0.29 (-0.54, 1.12)		-0.56 (-0.97, -0.16)	
p-value [3]		0.483		0.007	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	25	48	84	
Mean (StdDev)	1.5 (1.00)	2.3 (1.06)	2.5 (1.07)	2.0 (1.16)	
Median	1.5	2.0	2.5	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C5D1 CFB					
n	11	24	48	81	
LS Mean (StdErr) [2]	-0.98 (0.471)	-0.65 (0.295)	-0.20 (0.162)	-0.71 (0.131)	
95% CI [2]	-1.94, -0.02	-1.25, -0.05	-0.52, 0.12	-0.97, -0.45	
Difference (95% CI) in CFB [2]		0.33 (-0.73, 1.38)		-0.51 (-0.91, -0.11)	
p-value [3]		0.533		0.013	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	25	46	86	
Mean (StdDev)	1.3 (1.30)	2.1 (1.09)	2.6 (1.08)	1.8 (1.16)	
Median	1.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	11	24	46	83	
LS Mean (StdErr) [2]	-1.04 (0.507)	-0.81 (0.317)	-0.04 (0.161)	-0.82 (0.127)	
95% CI [2]	-2.08, -0.01	-1.46, -0.16	-0.36, 0.28	-1.07, -0.57	
Difference (95% CI) in CFB [2]		0.23 (-0.90, 1.37)		-0.77 (-1.17, -0.38)	
p-value [3]		0.677		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	11	24	47	87	
Mean (StdDev)	1.8 (1.40)	2.2 (0.98)	2.4 (1.19)	1.8 (1.19)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	10	23	47	84	
LS Mean (StdErr) [2]	-0.29 (0.455)	-0.61 (0.278)	-0.27 (0.164)	-0.89 (0.127)	
95% CI [2]	-1.22, 0.63	-1.18, -0.04	-0.59, 0.05	-1.14, -0.64	
Difference (95% CI) in CFB [2]		-0.32 (-1.34, 0.71)		-0.62 (-1.02, -0.23)	
Hedges'G (95% CI) in CFB		-0.23 (-1.02, 0.53)		-0.54 (-0.91, -0.18)	
p-value [3]		0.531		0.002	
					0.502

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	12	25	53	94	
Mean (StdDev)	2.1 (1.16)	2.2 (1.41)	2.3 (1.39)	2.0 (1.29)	
Median	2.0	3.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	52	94	
Mean (StdDev)	1.4 (0.77)	1.8 (1.18)	2.1 (1.36)	1.6 (1.36)	
Median	1.0	2.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C2D1 CFB					
n	12	24	51	92	
LS Mean (StdErr) [2]	-0.67 (0.388)	-0.25 (0.246)	-0.11 (0.130)	-0.31 (0.103)	
95% CI [2]	-1.46, 0.12	-0.75, 0.25	-0.37, 0.15	-0.51, -0.11	
Difference (95% CI) in CFB [2]		0.42 (-0.46, 1.30)		-0.20 (-0.52, 0.12)	
p-value [3]		0.340		0.218	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	24	49	86	
Mean (StdDev)	1.2 (1.09)	1.7 (1.09)	1.9 (1.28)	1.4 (1.26)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	12	24	48	85	
LS Mean (StdErr) [2]	-0.75 (0.343)	-0.47 (0.217)	-0.36 (0.153)	-0.47 (0.120)	
95% CI [2]	-1.45, -0.05	-0.92, -0.03	-0.66, -0.06	-0.70, -0.23	
Difference (95% CI) in CFB [2]		0.27 (-0.51, 1.06)		-0.10 (-0.47, 0.27)	
p-value [3]		0.482		0.578	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	11	22	45	91	
Mean (StdDev)	0.7 (1.01)	1.9 (1.17)	2.0 (1.31)	1.5 (1.34)	
Median	0.0	2.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C4D1 CFB					
n	10	22	44	89	
LS Mean (StdErr) [2]	-1.31 (0.402)	-0.51 (0.254)	-0.25 (0.172)	-0.50 (0.127)	
95% CI [2]	-2.14, -0.49	-1.03, 0.01	-0.59, 0.09	-0.75, -0.24	
Difference (95% CI) in CFB [2]		0.81 (-0.09, 1.71)		-0.25 (-0.66, 0.16)	
p-value [3]		0.077		0.232	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	25	48	84	
Mean (StdDev)	0.8 (0.72)	1.5 (1.12)	1.9 (1.37)	1.3 (1.30)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	
C5D1 CFB					
n	11	24	48	81	
LS Mean (StdErr) [2]	-1.15 (0.415)	-0.65 (0.260)	-0.31 (0.174)	-0.70 (0.142)	
95% CI [2]	-1.99, -0.30	-1.18, -0.12	-0.66, 0.03	-0.98, -0.42	
Difference (95% CI) in CFB [2]		0.50 (-0.43, 1.42)		-0.39 (-0.82, 0.04)	
p-value [3]		0.286		0.077	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	25	46	86	
Mean (StdDev)	0.9 (0.79)	1.5 (1.08)	2.2 (1.42)	1.3 (1.24)	
Median	1.0	2.0	3.0	1.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	
C6D1 CFB					
n	11	24	46	83	
LS Mean (StdErr) [2]	-1.30 (0.455)	-0.79 (0.285)	0.01 (0.170)	-0.65 (0.134)	
95% CI [2]	-2.23, -0.38	-1.37, -0.22	-0.33, 0.35	-0.92, -0.39	
Difference (95% CI) in CFB [2]		0.51 (-0.51, 1.53)		-0.66 (-1.08, -0.25)	
p-value [3]		0.316		0.002	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	11	24	47	87	
Mean (StdDev)	1.2 (0.75)	1.4 (1.18)	2.0 (1.44)	1.2 (1.34)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	
C7D1 CFB					
n	10	23	47	84	
LS Mean (StdErr) [2]	-0.70 (0.364)	-0.65 (0.223)	-0.29 (0.167)	-0.69 (0.129)	
95% CI [2]	-1.44, 0.04	-1.10, -0.19	-0.62, 0.04	-0.94, -0.43	
Difference (95% CI) in CFB [2]		0.05 (-0.77, 0.87)		-0.39 (-0.80, 0.01)	
Hedges'G (95% CI) in CFB		0.05 (-0.72, 0.82)		-0.33 (-0.70, 0.02)	
p-value [3]		0.895		0.056	
					0.504

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	12	25	53	94	
Mean (StdDev)	2.1 (0.90)	2.7 (1.31)	2.5 (1.03)	2.4 (1.00)	
Median	2.0	3.0	3.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	52	94	
Mean (StdDev)	1.6 (0.87)	1.9 (1.05)	2.0 (1.09)	1.8 (1.16)	
Median	1.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	12	24	51	92	
LS Mean (StdErr) [2]	-0.41 (0.445)	-0.75 (0.282)	-0.45 (0.142)	-0.69 (0.112)	
95% CI [2]	-1.31, 0.50	-1.32, -0.17	-0.73, -0.17	-0.91, -0.47	
Difference (95% CI) in CFB [2]		-0.34 (-1.35, 0.67)		-0.24 (-0.59, 0.11)	
p-value [3]		0.499		0.171	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	24	50	85	
Mean (StdDev)	1.7 (1.18)	1.9 (0.97)	2.1 (1.10)	1.6 (1.09)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	12	24	49	84	
LS Mean (StdErr) [2]	-0.48 (0.363)	-0.75 (0.230)	-0.48 (0.168)	-0.89 (0.133)	
95% CI [2]	-1.22, 0.25	-1.21, -0.28	-0.81, -0.15	-1.16, -0.63	
Difference (95% CI) in CFB [2]		-0.26 (-1.09, 0.57)		-0.41 (-0.82, -0.01)	
p-value [3]		0.525		0.047	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	11	22	45	91	
Mean (StdDev)	1.4 (0.81)	2.1 (1.02)	2.0 (1.15)	1.6 (1.16)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C4D1 CFB					
n	10	22	44	89	
LS Mean (StdErr) [2]	-1.02 (0.353)	-0.83 (0.224)	-0.49 (0.178)	-0.94 (0.131)	
95% CI [2]	-1.74, -0.30	-1.28, -0.37	-0.84, -0.14	-1.20, -0.68	
Difference (95% CI) in CFB [2]		0.19 (-0.60, 0.98)		-0.45 (-0.87, -0.03)	
p-value [3]		0.623		0.038	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	25	48	84	
Mean (StdDev)	1.2 (0.72)	1.8 (1.00)	2.0 (1.20)	1.5 (1.18)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	
C5D1 CFB					
n	11	24	48	81	
LS Mean (StdErr) [2]	-1.04 (0.392)	-0.93 (0.245)	-0.52 (0.182)	-1.10 (0.148)	
95% CI [2]	-1.84, -0.25	-1.43, -0.43	-0.88, -0.16	-1.39, -0.80	
Difference (95% CI) in CFB [2]		0.11 (-0.77, 0.99)		-0.57 (-1.02, -0.13)	
p-value [3]		0.801		0.012	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	25	46	86	
Mean (StdDev)	1.3 (0.75)	1.6 (1.12)	2.1 (1.18)	1.5 (1.17)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	
C6D1 CFB					
n	11	24	46	83	
LS Mean (StdErr) [2]	-0.89 (0.394)	-1.16 (0.247)	-0.34 (0.178)	-1.02 (0.140)	
95% CI [2]	-1.70, -0.09	-1.66, -0.66	-0.69, 0.01	-1.30, -0.74	
Difference (95% CI) in CFB [2]		-0.27 (-1.15, 0.61)		-0.68 (-1.12, -0.25)	
p-value [3]		0.542		0.002	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	11	24	47	87	
Mean (StdDev)	1.1 (0.70)	2.0 (1.27)	2.1 (1.31)	1.4 (1.26)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	
C7D1 CFB					
n	10	23	47	84	
LS Mean (StdErr) [2]	-0.88 (0.493)	-0.77 (0.302)	-0.43 (0.195)	-1.13 (0.151)	
95% CI [2]	-1.89, 0.12	-1.39, -0.16	-0.81, -0.04	-1.43, -0.83	
Difference (95% CI) in CFB [2]		0.11 (-1.00, 1.22)		-0.71 (-1.18, -0.23)	
Hedges'G (95% CI) in CFB		0.07 (-0.69, 0.85)		-0.51 (-0.89, -0.16)	
p-value [3]		0.837		0.004	
					0.166

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	12	25	52	94	
Mean (StdDev)	1.8 (1.22)	2.3 (1.31)	2.2 (1.26)	2.2 (1.15)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	52	94	
Mean (StdDev)	1.0 (0.71)	2.0 (1.21)	2.1 (1.24)	1.7 (1.17)	
Median	1.0	2.0	2.0	2.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	
C2D1 CFB					
n	12	24	50	92	
LS Mean (StdErr) [2]	-0.85 (0.340)	-0.32 (0.216)	0.04 (0.146)	-0.43 (0.115)	
95% CI [2]	-1.55, -0.16	-0.76, 0.12	-0.25, 0.33	-0.65, -0.20	
Difference (95% CI) in CFB [2]		0.53 (-0.25, 1.31)		-0.47 (-0.83, -0.11)	
p-value [3]		0.173		0.011	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	24	50	86	
Mean (StdDev)	1.4 (1.26)	1.8 (1.22)	1.9 (1.17)	1.6 (1.07)	
Median	1.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	12	24	48	85	
LS Mean (StdErr) [2]	-0.36 (0.367)	-0.59 (0.232)	-0.14 (0.144)	-0.58 (0.113)	
95% CI [2]	-1.11, 0.39	-1.06, -0.12	-0.42, 0.15	-0.80, -0.36	
Difference (95% CI) in CFB [2]		-0.23 (-1.07, 0.61)		-0.44 (-0.79, -0.09)	
p-value [3]		0.578		0.013	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	11	22	45	91	
Mean (StdDev)	1.0 (0.89)	1.9 (1.15)	2.0 (1.24)	1.6 (1.27)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	
C4D1 CFB					
n	10	22	43	89	
LS Mean (StdErr) [2]	-0.55 (0.386)	-0.57 (0.244)	-0.11 (0.178)	-0.61 (0.131)	
95% CI [2]	-1.34, 0.24	-1.07, -0.07	-0.46, 0.24	-0.87, -0.35	
Difference (95% CI) in CFB [2]		-0.02 (-0.88, 0.84)		-0.50 (-0.92, -0.08)	
p-value [3]		0.964		0.021	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	25	48	84	
Mean (StdDev)	1.1 (0.90)	1.8 (1.16)	1.8 (1.12)	1.4 (1.14)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C5D1 CFB					
n	11	24	47	81	
LS Mean (StdErr) [2]	-0.44 (0.393)	-0.58 (0.246)	-0.25 (0.170)	-0.77 (0.137)	
95% CI [2]	-1.24, 0.36	-1.08, -0.08	-0.58, 0.09	-1.04, -0.50	
Difference (95% CI) in CFB [2]		-0.14 (-1.02, 0.74)		-0.52 (-0.94, -0.10)	
p-value [3]		0.748		0.015	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	25	46	86	
Mean (StdDev)	0.8 (0.72)	1.6 (1.22)	2.0 (1.19)	1.4 (1.22)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	
C6D1 CFB					
n	11	24	45	83	
LS Mean (StdErr) [2]	-0.87 (0.435)	-0.81 (0.272)	0.01 (0.172)	-0.73 (0.134)	
95% CI [2]	-1.76, 0.01	-1.37, -0.26	-0.33, 0.35	-1.00, -0.47	
Difference (95% CI) in CFB [2]		0.06 (-0.91, 1.03)		-0.74 (-1.16, -0.32)	
p-value [3]		0.902		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	11	24	47	87	
Mean (StdDev)	1.0 (1.00)	2.0 (1.12)	1.9 (1.17)	1.4 (1.28)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C7D1 CFB					
n	10	23	46	84	
LS Mean (StdErr) [2]	-0.36 (0.436)	-0.37 (0.267)	-0.18 (0.181)	-0.73 (0.140)	
95% CI [2]	-1.25, 0.53	-0.92, 0.17	-0.54, 0.18	-1.01, -0.45	
Difference (95% CI) in CFB [2]		-0.01 (-0.99, 0.97)		-0.55 (-0.99, -0.11)	
Hedges'G (95% CI) in CFB		-0.01 (-0.78, 0.76)		-0.43 (-0.81, -0.07)	
p-value [3]		0.982		0.014	
					0.399

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-tryp-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	61	110	4	9	
Mean (StdDev)	2.8 (1.07)	2.3 (1.11)	2.0 (1.83)	2.6 (0.88)	
Median	3.0	2.0	2.0	3.0	
Min, Max	0, 4	0, 4	0, 4	1, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	61	111	4	8	
Mean (StdDev)	2.3 (1.00)	1.6 (0.88)	2.0 (1.63)	2.1 (1.13)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	1, 4	
C2D1 CFB					
n	59	108	4	8	
LS Mean (StdErr) [2]	-0.42 (0.152)	-0.62 (0.121)	0.85 (1.016)	0.38 (0.801)	
95% CI [2]	-0.72, -0.12	-0.86, -0.38	-1.49, 3.20	-1.46, 2.23	
Difference (95% CI) in CFB [2]		-0.20 (-0.53, 0.13)		-0.47 (-2.51, 1.57)	
p-value [3]		0.241		0.609	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	59	102	4	8	
Mean (StdDev)	2.2 (1.12)	1.5 (0.89)	1.3 (0.96)	2.3 (1.28)	
Median	2.0	1.0	1.5	2.0	
Min, Max	0, 4	0, 3	0, 2	1, 4	
C3D1 CFB					
n	57	101	4	8	
LS Mean (StdErr) [2]	-0.59 (0.169)	-0.79 (0.133)	0.04 (0.892)	0.49 (0.704)	
95% CI [2]	-0.93, -0.26	-1.05, -0.53	-2.01, 2.10	-1.14, 2.11	
Difference (95% CI) in CFB [2]		-0.20 (-0.57, 0.17)		0.44 (-1.35, 2.23)	
p-value [3]		0.293		0.585	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	52	104	4	9	
Mean (StdDev)	2.3 (1.05)	1.4 (1.02)	2.0 (1.63)	2.0 (1.00)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	1, 3	
C4D1 CFB					
n	50	102	4	9	
LS Mean (StdErr) [2]	-0.50 (0.185)	-0.92 (0.142)	0.38 (1.015)	-0.12 (0.804)	
95% CI [2]	-0.86, -0.13	-1.20, -0.64	-1.92, 2.67	-1.94, 1.69	
Difference (95% CI) in CFB [2]		-0.42 (-0.82, -0.03)		-0.50 (-2.48, 1.48)	
p-value [3]		0.036		0.582	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	56	99	4	9	
Mean (StdDev)	2.3 (1.20)	1.3 (0.98)	1.5 (1.00)	1.6 (0.88)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 2	1, 3	
C5D1 CFB					
n	55	95	4	9	
LS Mean (StdErr) [2]	-0.38 (0.186)	-0.89 (0.148)	0.22 (0.759)	-0.07 (0.602)	
95% CI [2]	-0.75, -0.01	-1.18, -0.59	-1.49, 1.94	-1.44, 1.29	
Difference (95% CI) in CFB [2]		-0.50 (-0.91, -0.10)		-0.30 (-1.78, 1.18)	
p-value [3]		0.016		0.658	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	102	4	9	
Mean (StdDev)	2.2 (1.21)	1.4 (1.02)	1.5 (1.00)	2.2 (0.83)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 2	1, 3	
C6D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-0.54 (0.183)	-0.89 (0.143)	-0.22 (0.759)	0.08 (0.602)	
95% CI [2]	-0.91, -0.18	-1.18, -0.61	-1.94, 1.49	-1.29, 1.44	
Difference (95% CI) in CFB [2]		-0.35 (-0.75, 0.05)		0.30 (-1.18, 1.78)	
p-value [3]		0.086		0.658	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	54	102	4	9	
Mean (StdDev)	2.4 (1.14)	1.3 (0.94)	1.5 (1.00)	1.9 (0.93)	
Median	2.5	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 2	1, 3	
C7D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-0.35 (0.174)	-0.90 (0.133)	-0.00 (0.847)	-0.00 (0.671)	
95% CI [2]	-0.70, -0.01	-1.16, -0.63	-1.92, 1.92	-1.52, 1.52	
Difference (95% CI) in CFB [2]		-0.55 (-0.92, -0.17)		0.00 (-1.65, 1.65)	
Hedges'G (95% CI) in CFB		-0.42 (-0.76, -0.08)		0.00 (-1.32, 1.32)	
p-value [3]		0.005		>0.999	
					0.409

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	61	110	4	9	
Mean (StdDev)	2.5 (1.15)	2.1 (1.15)	2.0 (1.41)	2.7 (0.87)	
Median	3.0	2.0	2.5	2.0	
Min, Max	0, 4	0, 4	0, 3	2, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	61	111	4	8	
Mean (StdDev)	2.2 (1.12)	1.4 (0.97)	1.8 (1.26)	2.0 (1.20)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 3	0, 4	
C2D1 CFB					
n	59	108	4	8	
LS Mean (StdErr) [2]	-0.16 (0.166)	-0.56 (0.132)	-0.54 (0.892)	-0.99 (0.704)	
95% CI [2]	-0.49, 0.17	-0.82, -0.29	-2.60, 1.51	-2.61, 0.64	
Difference (95% CI) in CFB [2]		-0.39 (-0.76, -0.03)		-0.44 (-2.23, 1.35)	
p-value [3]		0.034		0.585	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	59	102	4	8	
Mean (StdDev)	2.2 (1.22)	1.4 (0.99)	2.0 (1.63)	2.0 (1.07)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 3	
C3D1 CFB					
n	57	101	4	8	
LS Mean (StdErr) [2]	-0.33 (0.182)	-0.60 (0.143)	-0.79 (0.724)	-1.24 (0.571)	
95% CI [2]	-0.69, 0.03	-0.89, -0.32	-2.46, 0.88	-2.55, 0.08	
Difference (95% CI) in CFB [2]		-0.27 (-0.67, 0.13)		-0.44 (-1.89, 1.01)	
p-value [3]		0.178		0.503	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	52	104	4	9	
Mean (StdDev)	2.2 (1.05)	1.3 (1.03)	2.0 (1.41)	1.8 (1.09)	
Median	2.0	1.0	2.5	2.0	
Min, Max	0, 4	0, 4	0, 3	0, 3	
C4D1 CFB					
n	50	102	4	9	
LS Mean (StdErr) [2]	-0.21 (0.184)	-0.70 (0.141)	-0.65 (0.895)	-1.45 (0.709)	
95% CI [2]	-0.57, 0.15	-0.98, -0.42	-2.67, 1.37	-3.05, 0.15	
Difference (95% CI) in CFB [2]		-0.49 (-0.88, -0.10)		-0.80 (-2.55, 0.95)	
p-value [3]		0.015		0.327	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	56	99	4	9	
Mean (StdDev)	2.1 (1.27)	1.3 (0.96)	1.5 (1.29)	1.7 (1.22)	
Median	2.0	1.0	1.5	1.0	
Min, Max	0, 4	0, 4	0, 3	0, 4	
C5D1 CFB					
n	55	95	4	9	
LS Mean (StdErr) [2]	-0.20 (0.180)	-0.59 (0.143)	-0.50 (1.008)	-1.00 (0.798)	
95% CI [2]	-0.56, 0.15	-0.87, -0.31	-2.78, 1.78	-2.81, 0.81	
Difference (95% CI) in CFB [2]		-0.38 (-0.78, 0.01)		-0.50 (-2.47, 1.47)	
p-value [3]		0.058		0.579	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	102	4	9	
Mean (StdDev)	2.2 (1.18)	1.4 (1.03)	1.8 (1.26)	2.1 (1.54)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 3	0, 4	
C6D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-0.13 (0.182)	-0.57 (0.142)	-1.10 (1.048)	-1.30 (0.831)	
95% CI [2]	-0.49, 0.22	-0.85, -0.29	-3.47, 1.27	-3.18, 0.58	
Difference (95% CI) in CFB [2]		-0.44 (-0.84, -0.04)		-0.20 (-2.25, 1.85)	
p-value [3]		0.033		0.830	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	54	102	4	9	
Mean (StdDev)	2.2 (1.19)	1.4 (1.06)	1.8 (1.26)	1.8 (1.39)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 3	0, 4	
C7D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-0.10 (0.187)	-0.50 (0.144)	-0.35 (1.182)	-1.05 (0.937)	
95% CI [2]	-0.46, 0.27	-0.78, -0.21	-3.02, 2.32	-3.17, 1.07	
Difference (95% CI) in CFB [2]		-0.40 (-0.80, 0.00)		-0.70 (-3.01, 1.61)	
Hedges'G (95% CI) in CFB		-0.28 (-0.63, 0.05)		-0.24 (-1.62, 1.03)	
p-value [3]		0.052		0.510	
					0.893

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	61	110	4	9	
Mean (StdDev)	2.4 (1.08)	2.4 (1.07)	1.0 (1.41)	2.2 (1.30)	
Median	2.0	2.0	0.5	2.0	
Min, Max	0, 4	0, 4	0, 3	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	61	111	4	8	
Mean (StdDev)	2.1 (1.07)	1.9 (1.09)	1.3 (1.26)	1.6 (0.74)	
Median	2.0	2.0	1.0	1.5	
Min, Max	0, 4	0, 4	0, 3	1, 3	
C2D1 CFB					
n	59	108	4	8	
LS Mean (StdErr) [2]	-0.19 (0.149)	-0.42 (0.119)	0.01 (0.548)	-0.34 (0.432)	
95% CI [2]	-0.48, 0.11	-0.65, -0.18	-1.25, 1.28	-1.33, 0.66	
Difference (95% CI) in CFB [2]		-0.23 (-0.56, 0.10)		-0.35 (-1.45, 0.75)	
p-value [3]		0.166		0.480	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	59	102	4	8	
Mean (StdDev)	2.0 (1.02)	1.8 (1.09)	1.5 (1.29)	2.0 (1.20)	
Median	2.0	2.0	1.5	1.5	
Min, Max	0, 4	0, 4	0, 3	1, 4	
C3D1 CFB					
n	57	101	4	8	
LS Mean (StdErr) [2]	-0.21 (0.167)	-0.50 (0.131)	1.21 (0.623)	0.76 (0.491)	
95% CI [2]	-0.54, 0.12	-0.76, -0.24	-0.23, 2.64	-0.37, 1.90	
Difference (95% CI) in CFB [2]		-0.29 (-0.66, 0.07)		-0.44 (-1.69, 0.81)	
p-value [3]		0.116		0.439	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	52	104	4	9	
Mean (StdDev)	2.2 (1.06)	1.7 (1.00)	1.3 (1.89)	2.2 (1.30)	
Median	2.0	2.0	0.5	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	50	102	4	9	
LS Mean (StdErr) [2]	-0.14 (0.176)	-0.57 (0.135)	0.95 (0.867)	0.85 (0.687)	
95% CI [2]	-0.49, 0.21	-0.84, -0.31	-1.01, 2.91	-0.70, 2.40	
Difference (95% CI) in CFB [2]		-0.43 (-0.81, -0.05)		-0.10 (-1.79, 1.59)	
p-value [3]		0.025		0.897	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	56	99	4	9	
Mean (StdDev)	2.0 (1.19)	1.7 (1.03)	2.5 (1.91)	2.2 (1.48)	
Median	2.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	55	95	4	9	
LS Mean (StdErr) [2]	-0.27 (0.174)	-0.57 (0.138)	0.55 (1.025)	-0.35 (0.812)	
95% CI [2]	-0.61, 0.07	-0.84, -0.30	-1.77, 2.87	-2.19, 1.49	
Difference (95% CI) in CFB [2]		-0.30 (-0.68, 0.08)		-0.90 (-2.90, 1.10)	
p-value [3]		0.126		0.335	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	102	4	9	
Mean (StdDev)	1.9 (1.19)	1.6 (1.09)	2.0 (1.41)	2.3 (1.50)	
Median	2.0	2.0	2.5	2.0	
Min, Max	0, 4	0, 4	0, 3	0, 4	
C6D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-0.31 (0.175)	-0.63 (0.137)	2.13 (0.782)	1.13 (0.620)	
95% CI [2]	-0.65, 0.04	-0.90, -0.36	0.36, 3.89	-0.28, 2.53	
Difference (95% CI) in CFB [2]		-0.32 (-0.71, 0.06)		-1.00 (-2.53, 0.53)	
p-value [3]		0.099		0.173	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	54	102	4	9	
Mean (StdDev)	1.9 (1.11)	1.7 (1.09)	1.8 (1.50)	2.0 (1.32)	
Median	2.0	1.5	2.0	2.0	
Min, Max	0, 4	0, 4	0, 3	0, 4	
C7D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-0.36 (0.192)	-0.63 (0.148)	0.88 (0.702)	-0.13 (0.556)	
95% CI [2]	-0.74, 0.02	-0.92, -0.34	-0.71, 2.46	-1.38, 1.13	
Difference (95% CI) in CFB [2]		-0.27 (-0.68, 0.15)		-1.00 (-2.37, 0.37)	
Hedges'G (95% CI) in CFB		-0.19 (-0.53, 0.15)		-0.58 (-2.07, 0.64)	
p-value [3]		0.205		0.133	
					0.405

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	61	110	4	9	
Mean (StdDev)	2.1 (1.20)	2.2 (1.21)	2.8 (1.26)	2.0 (1.41)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	61	110	4	8	
Mean (StdDev)	1.7 (1.16)	1.5 (1.09)	2.0 (1.41)	2.0 (1.60)	
Median	2.0	1.0	1.5	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C2D1 CFB					
n	59	107	4	8	
LS Mean (StdErr) [2]	-0.25 (0.168)	-0.53 (0.136)	-0.60 (0.982)	-0.13 (0.774)	
95% CI [2]	-0.58, 0.08	-0.80, -0.26	-2.87, 1.66	-1.92, 1.65	
Difference (95% CI) in CFB [2]		-0.28 (-0.65, 0.09)		0.47 (-1.50, 2.44)	
p-value [3]		0.134		0.597	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	59	102	4	8	
Mean (StdDev)	1.7 (1.29)	1.5 (1.11)	2.8 (0.96)	1.9 (1.64)	
Median	1.0	1.0	2.5	1.5	
Min, Max	0, 4	0, 4	2, 4	0, 4	
C3D1 CFB					
n	57	101	4	8	
LS Mean (StdErr) [2]	-0.20 (0.187)	-0.52 (0.147)	0.15 (1.081)	-0.38 (0.852)	
95% CI [2]	-0.57, 0.17	-0.81, -0.23	-2.35, 2.64	-2.35, 1.58	
Difference (95% CI) in CFB [2]		-0.32 (-0.73, 0.09)		-0.53 (-2.70, 1.64)	
p-value [3]		0.129		0.589	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	52	104	4	9	
Mean (StdDev)	1.7 (1.21)	1.5 (1.17)	2.8 (0.96)	1.2 (1.39)	
Median	2.0	1.0	2.5	1.0	
Min, Max	0, 4	0, 4	2, 4	0, 4	
C4D1 CFB					
n	50	102	4	9	
LS Mean (StdErr) [2]	-0.36 (0.186)	-0.53 (0.142)	0.42 (1.003)	-0.48 (0.795)	
95% CI [2]	-0.73, 0.01	-0.81, -0.25	-1.84, 2.69	-2.27, 1.32	
Difference (95% CI) in CFB [2]		-0.17 (-0.57, 0.23)		-0.90 (-2.86, 1.06)	
p-value [3]		0.394		0.325	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	56	99	4	9	
Mean (StdDev)	1.8 (1.12)	1.4 (1.14)	2.3 (0.50)	1.3 (1.41)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	2, 3	0, 3	
C5D1 CFB					
n	55	95	4	9	
LS Mean (StdErr) [2]	-0.12 (0.189)	-0.65 (0.150)	-0.15 (0.861)	-0.45 (0.682)	
95% CI [2]	-0.49, 0.26	-0.95, -0.36	-2.10, 1.80	-1.99, 1.09	
Difference (95% CI) in CFB [2]		-0.54 (-0.95, -0.12)		-0.30 (-1.98, 1.38)	
p-value [3]		0.012		0.696	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	102	4	9	
Mean (StdDev)	1.7 (1.17)	1.4 (1.13)	2.0 (1.63)	1.0 (1.32)	
Median	2.0	1.0	2.0	0.0	
Min, Max	0, 4	0, 4	0, 4	0, 3	
C6D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-0.14 (0.186)	-0.59 (0.145)	-0.15 (1.019)	-0.45 (0.808)	
95% CI [2]	-0.51, 0.23	-0.88, -0.30	-2.46, 2.16	-2.28, 1.38	
Difference (95% CI) in CFB [2]		-0.45 (-0.86, -0.04)		-0.30 (-2.29, 1.69)	
p-value [3]		0.031		0.741	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	54	102	4	9	
Mean (StdDev)	1.7 (1.09)	1.4 (1.22)	1.8 (1.26)	1.3 (1.58)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 3	0, 4	
C7D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-0.06 (0.190)	-0.50 (0.146)	-0.60 (0.959)	-0.30 (0.760)	
95% CI [2]	-0.43, 0.32	-0.79, -0.21	-2.77, 1.57	-2.02, 1.42	
Difference (95% CI) in CFB [2]		-0.44 (-0.85, -0.03)		0.30 (-1.57, 2.17)	
Hedges'G (95% CI) in CFB		-0.31 (-0.65, 0.03)		0.13 (-1.17, 1.48)	
p-value [3]		0.037		0.725	
					0.259

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	61	110	4	9	
Mean (StdDev)	3.1 (0.93)	3.3 (0.86)	3.8 (0.50)	3.2 (0.97)	
Median	3.0	3.0	4.0	3.0	
Min, Max	1, 4	1, 4	3, 4	1, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	61	111	4	8	
Mean (StdDev)	2.8 (0.97)	2.7 (1.09)	3.3 (0.50)	2.9 (0.99)	
Median	3.0	3.0	3.0	3.0	
Min, Max	1, 4	0, 4	3, 4	1, 4	
C2D1 CFB					
n	59	108	4	8	
LS Mean (StdErr) [2]	-0.34 (0.141)	-0.55 (0.112)	-0.97 (0.620)	-0.68 (0.489)	
95% CI [2]	-0.61, -0.06	-0.77, -0.33	-2.40, 0.46	-1.80, 0.45	
Difference (95% CI) in CFB [2]		-0.22 (-0.52, 0.09)		0.29 (-0.95, 1.54)	
p-value [3]		0.168		0.600	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	59	102	4	8	
Mean (StdDev)	2.6 (1.11)	2.5 (1.09)	3.3 (0.96)	3.0 (1.07)	
Median	3.0	3.0	3.5	3.0	
Min, Max	0, 4	0, 4	2, 4	1, 4	
C3D1 CFB					
n	57	101	4	8	
LS Mean (StdErr) [2]	-0.41 (0.162)	-0.73 (0.127)	-0.53 (0.767)	-0.32 (0.605)	
95% CI [2]	-0.73, -0.09	-0.99, -0.48	-2.30, 1.24	-1.72, 1.07	
Difference (95% CI) in CFB [2]		-0.33 (-0.68, 0.03)		0.21 (-1.33, 1.74)	
p-value [3]		0.070		0.766	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	52	104	4	9	
Mean (StdDev)	2.7 (1.14)	2.5 (1.11)	3.5 (0.58)	3.0 (1.00)	
Median	3.0	3.0	3.5	3.0	
Min, Max	1, 4	0, 4	3, 4	1, 4	
C4D1 CFB					
n	50	102	4	9	
LS Mean (StdErr) [2]	-0.41 (0.174)	-0.71 (0.133)	-0.75 (1.008)	-0.75 (0.798)	
95% CI [2]	-0.75, -0.06	-0.97, -0.44	-3.03, 1.53	-2.56, 1.06	
Difference (95% CI) in CFB [2]		-0.30 (-0.67, 0.07)		0.00 (-1.97, 1.97)	
p-value [3]		0.114		>0.999	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	56	99	4	9	
Mean (StdDev)	2.7 (1.22)	2.4 (1.16)	3.3 (0.96)	3.0 (1.00)	
Median	3.0	2.0	3.5	3.0	
Min, Max	0, 4	0, 4	2, 4	1, 4	
C5D1 CFB					
n	55	95	4	9	
LS Mean (StdErr) [2]	-0.37 (0.168)	-0.83 (0.134)	-1.08 (0.876)	-0.98 (0.694)	
95% CI [2]	-0.70, -0.03	-1.09, -0.56	-3.06, 0.91	-2.55, 0.60	
Difference (95% CI) in CFB [2]		-0.46 (-0.83, -0.09)		0.10 (-1.61, 1.81)	
p-value [3]		0.015		0.898	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	102	4	9	
Mean (StdDev)	2.6 (1.09)	2.3 (1.19)	3.8 (0.50)	3.1 (0.93)	
Median	3.0	2.0	4.0	3.0	
Min, Max	0, 4	0, 4	3, 4	2, 4	
C6D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-0.54 (0.174)	-0.91 (0.136)	-1.07 (0.876)	-0.98 (0.694)	
95% CI [2]	-0.89, -0.20	-1.18, -0.64	-3.06, 0.91	-2.55, 0.60	
Difference (95% CI) in CFB [2]		-0.37 (-0.75, 0.01)		0.10 (-1.61, 1.81)	
p-value [3]		0.057		0.898	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	54	102	4	9	
Mean (StdDev)	2.6 (1.09)	2.3 (1.13)	3.5 (0.58)	3.1 (0.78)	
Median	3.0	2.0	3.5	3.0	
Min, Max	0, 4	0, 4	3, 4	2, 4	
C7D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-0.48 (0.171)	-0.82 (0.131)	-0.77 (0.869)	-0.58 (0.689)	
95% CI [2]	-0.82, -0.14	-1.07, -0.56	-2.74, 1.19	-2.13, 0.98	
Difference (95% CI) in CFB [2]		-0.33 (-0.70, 0.04)		0.20 (-1.50, 1.90)	
Hedges'G (95% CI) in CFB		-0.26 (-0.60, 0.08)		0.09 (-1.21, 1.44)	
p-value [3]		0.077		0.796	
					0.446

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	61	110	4	9	
Mean (StdDev)	2.1 (1.13)	2.2 (1.05)	2.3 (1.26)	2.3 (1.00)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	1, 4	1, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	61	111	4	8	
Mean (StdDev)	2.0 (1.09)	1.9 (0.98)	2.0 (1.41)	1.9 (1.13)	
Median	2.0	2.0	1.5	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 3	
C2D1 CFB					
n	59	108	4	8	
LS Mean (StdErr) [2]	-0.14 (0.138)	-0.30 (0.110)	-0.10 (0.385)	-0.13 (0.303)	
95% CI [2]	-0.41, 0.13	-0.52, -0.09	-0.99, 0.78	-0.83, 0.57	
Difference (95% CI) in CFB [2]		-0.16 (-0.47, 0.14)		-0.03 (-0.80, 0.74)	
p-value [3]		0.288		0.932	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	59	102	4	8	
Mean (StdDev)	1.9 (1.10)	1.7 (0.95)	1.8 (1.50)	1.4 (1.30)	
Median	2.0	2.0	1.0	1.5	
Min, Max	0, 4	0, 4	1, 4	0, 3	
C3D1 CFB					
n	57	101	4	8	
LS Mean (StdErr) [2]	-0.23 (0.160)	-0.51 (0.125)	-0.68 (0.654)	-0.94 (0.516)	
95% CI [2]	-0.54, 0.09	-0.76, -0.26	-2.19, 0.83	-2.13, 0.25	
Difference (95% CI) in CFB [2]		-0.28 (-0.63, 0.07)		-0.26 (-1.58, 1.05)	
p-value [3]		0.115		0.654	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	52	104	4	9	
Mean (StdDev)	1.9 (1.15)	1.8 (1.13)	2.5 (1.73)	2.0 (1.50)	
Median	2.0	2.0	2.5	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C4D1 CFB					
n	50	102	4	9	
LS Mean (StdErr) [2]	-0.19 (0.175)	-0.34 (0.134)	-0.12 (0.782)	-0.63 (0.620)	
95% CI [2]	-0.54, 0.15	-0.60, -0.07	-1.89, 1.64	-2.03, 0.78	
Difference (95% CI) in CFB [2]		-0.14 (-0.52, 0.23)		-0.50 (-2.03, 1.03)	
p-value [3]		0.449		0.478	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	56	99	4	9	
Mean (StdDev)	1.9 (1.24)	1.7 (1.05)	2.0 (1.41)	2.1 (1.69)	
Median	2.0	2.0	1.5	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C5D1 CFB					
n	55	95	4	9	
LS Mean (StdErr) [2]	-0.22 (0.162)	-0.44 (0.129)	0.35 (0.568)	0.05 (0.450)	
95% CI [2]	-0.54, 0.10	-0.69, -0.18	-0.93, 1.63	-0.97, 1.07	
Difference (95% CI) in CFB [2]		-0.22 (-0.57, 0.14)		-0.30 (-1.41, 0.81)	
p-value [3]		0.230		0.555	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	102	4	9	
Mean (StdDev)	1.8 (1.07)	1.6 (1.07)	3.0 (0.82)	1.8 (1.92)	
Median	2.0	2.0	3.0	1.0	
Min, Max	0, 4	0, 4	2, 4	0, 4	
C6D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-0.31 (0.154)	-0.47 (0.121)	1.52 (0.630)	-0.18 (0.499)	
95% CI [2]	-0.61, -0.00	-0.70, -0.23	0.10, 2.95	-1.30, 0.95	
Difference (95% CI) in CFB [2]		-0.16 (-0.50, 0.18)		-1.70 (-2.93, -0.47)	
p-value [3]		0.352		0.012	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	54	102	4	9	
Mean (StdDev)	1.8 (1.11)	1.6 (1.08)	2.0 (0.82)	1.8 (1.30)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	1, 3	0, 4	
C7D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-0.31 (0.159)	-0.47 (0.122)	-0.58 (0.480)	-0.98 (0.380)	
95% CI [2]	-0.62, 0.01	-0.71, -0.23	-1.66, 0.51	-1.83, -0.12	
Difference (95% CI) in CFB [2]		-0.17 (-0.51, 0.18)		-0.40 (-1.34, 0.54)	
Hedges'G (95% CI) in CFB		-0.14 (-0.48, 0.20)		-0.34 (-1.75, 0.92)	
p-value [3]		0.343		0.359	
					0.800

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	61	110	4	9	
Mean (StdDev)	2.7 (1.18)	2.8 (1.15)	3.3 (0.96)	3.3 (0.71)	
Median	3.0	3.0	3.5	3.0	
Min, Max	0, 4	0, 4	2, 4	2, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	61	110	4	8	
Mean (StdDev)	2.3 (1.10)	2.2 (1.10)	2.8 (0.96)	2.9 (0.99)	
Median	2.0	2.0	2.5	3.0	
Min, Max	0, 4	0, 4	2, 4	1, 4	
C2D1 CFB					
n	59	107	4	8	
LS Mean (StdErr) [2]	-0.28 (0.137)	-0.44 (0.111)	-0.88 (0.400)	-0.71 (0.315)	
95% CI [2]	-0.55, -0.01	-0.66, -0.22	-1.80, 0.04	-1.43, 0.02	
Difference (95% CI) in CFB [2]		-0.16 (-0.46, 0.14)		0.18 (-0.63, 0.98)	
p-value [3]		0.299		0.626	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	59	102	4	8	
Mean (StdDev)	2.2 (1.14)	2.1 (1.21)	2.8 (1.26)	3.3 (0.71)	
Median	2.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	1, 4	2, 4	
C3D1 CFB					
n	57	101	4	8	
LS Mean (StdErr) [2]	-0.46 (0.168)	-0.63 (0.132)	-1.03 (0.335)	-0.32 (0.264)	
95% CI [2]	-0.79, -0.13	-0.89, -0.37	-1.80, -0.26	-0.93, 0.28	
Difference (95% CI) in CFB [2]		-0.17 (-0.54, 0.20)		0.71 (0.03, 1.38)	
p-value [3]		0.372		0.042	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	52	104	4	9	
Mean (StdDev)	2.4 (1.12)	2.1 (1.19)	3.3 (1.50)	3.4 (0.88)	
Median	2.5	2.0	4.0	4.0	
Min, Max	0, 4	0, 4	1, 4	2, 4	
C4D1 CFB					
n	50	102	4	9	
LS Mean (StdErr) [2]	-0.27 (0.191)	-0.60 (0.146)	-0.03 (0.630)	0.18 (0.499)	
95% CI [2]	-0.65, 0.10	-0.89, -0.31	-1.45, 1.40	-0.95, 1.30	
Difference (95% CI) in CFB [2]		-0.32 (-0.73, 0.09)		0.20 (-1.03, 1.43)	
p-value [3]		0.121		0.721	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	56	99	4	9	
Mean (StdDev)	2.4 (1.11)	2.1 (1.16)	3.0 (1.41)	3.6 (0.73)	
Median	3.0	2.0	3.5	4.0	
Min, Max	0, 4	0, 4	1, 4	2, 4	
C5D1 CFB					
n	55	95	4	9	
LS Mean (StdErr) [2]	-0.22 (0.164)	-0.58 (0.131)	-0.43 (0.480)	-0.03 (0.380)	
95% CI [2]	-0.55, 0.10	-0.84, -0.33	-1.51, 0.66	-0.88, 0.83	
Difference (95% CI) in CFB [2]		-0.36 (-0.72, -0.00)		0.40 (-0.54, 1.34)	
p-value [3]		0.049		0.359	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	102	4	9	
Mean (StdDev)	2.4 (1.22)	2.0 (1.18)	3.3 (0.96)	3.1 (1.05)	
Median	2.5	2.0	3.5	3.0	
Min, Max	0, 4	0, 4	2, 4	1, 4	
C6D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-0.28 (0.177)	-0.68 (0.138)	-0.43 (0.727)	-0.53 (0.576)	
95% CI [2]	-0.63, 0.07	-0.96, -0.41	-2.07, 1.22	-1.83, 0.78	
Difference (95% CI) in CFB [2]		-0.40 (-0.79, -0.01)		-0.10 (-1.52, 1.32)	
p-value [3]		0.043		0.877	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	54	102	4	9	
Mean (StdDev)	2.2 (1.18)	2.0 (1.13)	2.8 (1.50)	3.3 (1.12)	
Median	2.5	2.0	3.0	4.0	
Min, Max	0, 4	0, 4	1, 4	1, 4	
C7D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-0.32 (0.170)	-0.53 (0.131)	-0.45 (0.717)	0.15 (0.568)	
95% CI [2]	-0.65, 0.02	-0.79, -0.27	-2.07, 1.17	-1.13, 1.43	
Difference (95% CI) in CFB [2]		-0.21 (-0.58, 0.16)		0.60 (-0.80, 2.00)	
Hedges'G (95% CI) in CFB		-0.17 (-0.51, 0.17)		0.34 (-0.91, 1.75)	
p-value [3]		0.257		0.357	
					0.199

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	61	110	4	9	
Mean (StdDev)	2.2 (1.12)	2.7 (1.02)	3.3 (0.96)	2.3 (1.58)	
Median	2.0	3.0	3.5	3.0	
Min, Max	0, 4	0, 4	2, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	60	111	4	8	
Mean (StdDev)	2.1 (1.23)	2.1 (1.13)	2.8 (0.50)	1.3 (1.16)	
Median	2.0	2.0	3.0	1.5	
Min, Max	0, 4	0, 4	2, 3	0, 3	
C2D1 CFB					
n	58	108	4	8	
LS Mean (StdErr) [2]	-0.11 (0.127)	-0.52 (0.101)	-1.76 (1.057)	-1.91 (0.833)	
95% CI [2]	-0.36, 0.14	-0.72, -0.32	-4.20, 0.67	-3.83, 0.01	
Difference (95% CI) in CFB [2]		-0.41 (-0.69, -0.13)		-0.15 (-2.27, 1.97)	
p-value [3]		0.005		0.877	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	59	102	4	8	
Mean (StdDev)	2.1 (1.20)	1.9 (1.20)	2.3 (0.96)	1.6 (0.92)	
Median	2.0	2.0	2.5	2.0	
Min, Max	0, 4	0, 4	1, 3	0, 3	
C3D1 CFB					
n	57	101	4	8	
LS Mean (StdErr) [2]	-0.09 (0.127)	-0.72 (0.099)	-1.29 (1.034)	-0.74 (0.815)	
95% CI [2]	-0.34, 0.16	-0.92, -0.52	-3.68, 1.09	-2.61, 1.14	
Difference (95% CI) in CFB [2]		-0.63 (-0.91, -0.36)		0.56 (-1.51, 2.63)	
p-value [3]		<0.0001		0.552	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	52	104	4	9	
Mean (StdDev)	2.1 (1.19)	2.0 (1.18)	2.5 (0.58)	2.0 (1.22)	
Median	2.0	2.0	2.5	2.0	
Min, Max	0, 4	0, 4	2, 3	0, 4	
C4D1 CFB					
n	50	102	4	9	
LS Mean (StdErr) [2]	-0.10 (0.151)	-0.60 (0.116)	-1.13 (1.100)	-0.62 (0.871)	
95% CI [2]	-0.40, 0.20	-0.83, -0.37	-3.61, 1.36	-2.60, 1.35	
Difference (95% CI) in CFB [2]		-0.50 (-0.82, -0.18)		0.50 (-1.65, 2.65)	
p-value [3]		0.003		0.611	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	56	99	4	9	
Mean (StdDev)	2.1 (1.23)	1.9 (1.15)	2.5 (1.00)	2.2 (1.39)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	2, 4	0, 4	
C5D1 CFB					
n	55	95	4	9	
LS Mean (StdErr) [2]	-0.09 (0.148)	-0.72 (0.118)	-0.75 (1.120)	-0.25 (0.887)	
95% CI [2]	-0.38, 0.20	-0.95, -0.48	-3.28, 1.78	-2.26, 1.76	
Difference (95% CI) in CFB [2]		-0.63 (-0.95, -0.30)		0.50 (-1.69, 2.69)	
p-value [3]		<0.001		0.617	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	102	4	9	
Mean (StdDev)	1.9 (1.20)	1.8 (1.24)	3.3 (0.50)	1.9 (1.36)	
Median	2.0	2.0	3.0	1.0	
Min, Max	0, 4	0, 4	3, 4	0, 4	
C6D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-0.27 (0.157)	-0.79 (0.122)	0.25 (1.146)	-0.25 (0.908)	
95% CI [2]	-0.57, 0.04	-1.04, -0.55	-2.34, 2.84	-2.30, 1.80	
Difference (95% CI) in CFB [2]		-0.53 (-0.87, -0.19)		-0.50 (-2.74, 1.74)	
p-value [3]		0.003		0.625	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	54	102	4	9	
Mean (StdDev)	2.0 (1.18)	1.8 (1.26)	3.0 (0.82)	1.9 (1.27)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	2, 4	0, 4	
C7D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-0.10 (0.150)	-0.81 (0.115)	-0.60 (1.302)	-0.80 (1.032)	
95% CI [2]	-0.40, 0.19	-1.03, -0.58	-3.55, 2.35	-3.13, 1.53	
Difference (95% CI) in CFB [2]		-0.70 (-1.03, -0.38)		-0.20 (-2.74, 2.34)	
Hedges'G (95% CI) in CFB		-0.63 (-0.98, -0.29)		-0.06 (-1.40, 1.25)	
p-value [3]		<0.0001		0.863	
					0.389

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	61	110	4	9	
Mean (StdDev)	2.1 (1.33)	2.2 (1.43)	2.5 (1.73)	1.7 (1.66)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	61	111	4	8	
Mean (StdDev)	1.7 (1.34)	1.6 (1.39)	2.0 (2.31)	1.8 (1.67)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	59	108	4	8	
LS Mean (StdErr) [2]	-0.36 (0.195)	-0.53 (0.155)	-1.85 (1.569)	-0.88 (1.237)	
95% CI [2]	-0.75, 0.02	-0.84, -0.23	-5.47, 1.76	-3.73, 1.97	
Difference (95% CI) in CFB [2]		-0.17 (-0.60, 0.26)		0.97 (-2.18, 4.12)	
p-value [3]		0.437		0.497	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	59	101	4	8	
Mean (StdDev)	1.7 (1.33)	1.6 (1.36)	2.8 (0.50)	1.0 (1.60)	
Median	2.0	1.0	3.0	0.0	
Min, Max	0, 4	0, 4	2, 3	0, 4	
C3D1 CFB					
n	57	101	4	8	
LS Mean (StdErr) [2]	-0.33 (0.208)	-0.54 (0.163)	-1.37 (1.551)	-2.04 (1.223)	
95% CI [2]	-0.74, 0.08	-0.86, -0.22	-4.94, 2.21	-4.86, 0.78	
Difference (95% CI) in CFB [2]		-0.21 (-0.67, 0.24)		-0.68 (-3.79, 2.43)	
p-value [3]		0.353		0.630	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	52	104	4	9	
Mean (StdDev)	1.8 (1.19)	1.5 (1.31)	3.3 (0.50)	1.8 (1.56)	
Median	2.0	1.0	3.0	2.0	
Min, Max	0, 4	0, 4	3, 4	0, 4	
C4D1 CFB					
n	50	102	4	9	
LS Mean (StdErr) [2]	-0.26 (0.227)	-0.63 (0.174)	-1.08 (1.142)	-1.47 (0.905)	
95% CI [2]	-0.70, 0.19	-0.98, -0.29	-3.66, 1.51	-3.52, 0.57	
Difference (95% CI) in CFB [2]		-0.38 (-0.87, 0.11)		-0.40 (-2.63, 1.83)	
p-value [3]		0.125		0.694	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	55	100	4	9	
Mean (StdDev)	1.8 (1.22)	1.4 (1.29)	3.0 (0.00)	1.9 (1.45)	
Median	2.0	1.0	3.0	2.0	
Min, Max	0, 4	0, 4	3, 3	0, 4	
C5D1 CFB					
n	54	96	4	9	
LS Mean (StdErr) [2]	-0.17 (0.210)	-0.83 (0.166)	-0.80 (1.307)	-0.90 (1.036)	
95% CI [2]	-0.59, 0.24	-1.16, -0.50	-3.76, 2.16	-3.24, 1.44	
Difference (95% CI) in CFB [2]		-0.66 (-1.12, -0.19)		-0.10 (-2.65, 2.45)	
p-value [3]		0.006		0.931	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	102	4	9	
Mean (StdDev)	1.9 (1.27)	1.4 (1.33)	3.3 (0.50)	2.0 (1.32)	
Median	2.0	1.0	3.0	2.0	
Min, Max	0, 4	0, 4	3, 4	0, 4	
C6D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-0.18 (0.211)	-0.65 (0.165)	-0.70 (1.330)	-1.10 (1.054)	
95% CI [2]	-0.59, 0.24	-0.98, -0.33	-3.71, 2.31	-3.48, 1.28	
Difference (95% CI) in CFB [2]		-0.48 (-0.94, -0.01)		-0.40 (-2.99, 2.19)	
p-value [3]		0.044		0.735	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	54	102	4	9	
Mean (StdDev)	1.6 (1.27)	1.4 (1.30)	3.3 (0.50)	1.9 (1.45)	
Median	1.5	1.0	3.0	2.0	
Min, Max	0, 4	0, 4	3, 4	0, 4	
C7D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-0.27 (0.212)	-0.67 (0.163)	-0.05 (1.162)	-0.65 (0.921)	
95% CI [2]	-0.68, 0.15	-0.99, -0.35	-2.68, 2.58	-2.73, 1.43	
Difference (95% CI) in CFB [2]		-0.40 (-0.86, 0.05)		-0.60 (-2.87, 1.67)	
Hedges'G (95% CI) in CFB		-0.25 (-0.60, 0.08)		-0.21 (-1.59, 1.07)	
p-value [3]		0.083		0.564	
					0.906

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	61	110	4	9	
Mean (StdDev)	2.5 (1.22)	2.6 (1.32)	3.0 (2.00)	3.3 (0.71)	
Median	3.0	3.0	4.0	3.0	
Min, Max	0, 4	0, 4	0, 4	2, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	61	111	4	8	
Mean (StdDev)	2.2 (1.23)	2.1 (1.33)	3.5 (0.58)	2.4 (0.92)	
Median	2.0	2.0	3.5	2.0	
Min, Max	0, 4	0, 4	3, 4	1, 4	
C2D1 CFB					
n	59	108	4	8	
LS Mean (StdErr) [2]	-0.22 (0.167)	-0.48 (0.133)	0.29 (0.892)	-1.26 (0.704)	
95% CI [2]	-0.54, 0.11	-0.75, -0.22	-1.76, 2.35	-2.89, 0.36	
Difference (95% CI) in CFB [2]		-0.27 (-0.64, 0.10)		-1.56 (-3.35, 0.23)	
p-value [3]		0.148		0.079	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	59	101	4	8	
Mean (StdDev)	2.3 (1.21)	1.8 (1.29)	3.3 (0.50)	2.4 (1.30)	
Median	2.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	3, 4	0, 4	
C3D1 CFB					
n	57	101	4	8	
LS Mean (StdErr) [2]	-0.19 (0.174)	-0.71 (0.136)	-0.57 (0.914)	-1.81 (0.721)	
95% CI [2]	-0.54, 0.15	-0.98, -0.44	-2.68, 1.54	-3.47, -0.15	
Difference (95% CI) in CFB [2]		-0.52 (-0.90, -0.14)		-1.24 (-3.07, 0.60)	
p-value [3]		0.008		0.159	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	52	104	4	9	
Mean (StdDev)	2.1 (1.32)	1.9 (1.32)	3.3 (0.50)	2.8 (1.39)	
Median	2.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	3, 4	0, 4	
C4D1 CFB					
n	50	102	4	9	
LS Mean (StdErr) [2]	-0.29 (0.195)	-0.64 (0.149)	-0.65 (0.959)	-1.45 (0.760)	
95% CI [2]	-0.68, 0.09	-0.93, -0.35	-2.82, 1.52	-3.17, 0.27	
Difference (95% CI) in CFB [2]		-0.35 (-0.76, 0.07)		-0.80 (-2.67, 1.07)	
p-value [3]		0.101		0.359	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	55	100	4	9	
Mean (StdDev)	2.1 (1.23)	1.7 (1.22)	3.3 (0.50)	2.4 (1.42)	
Median	2.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	3, 4	0, 4	
C5D1 CFB					
n	54	96	4	9	
LS Mean (StdErr) [2]	-0.24 (0.184)	-0.83 (0.145)	0.05 (1.162)	-1.35 (0.921)	
95% CI [2]	-0.61, 0.12	-1.12, -0.55	-2.58, 2.68	-3.43, 0.73	
Difference (95% CI) in CFB [2]		-0.59 (-1.00, -0.19)		-1.40 (-3.67, 0.87)	
p-value [3]		0.004		0.196	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	102	4	9	
Mean (StdDev)	2.3 (1.26)	1.7 (1.32)	3.5 (0.58)	2.7 (1.00)	
Median	2.0	2.0	3.5	3.0	
Min, Max	0, 4	0, 4	3, 4	1, 4	
C6D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-0.07 (0.189)	-0.79 (0.148)	0.75 (0.978)	-0.75 (0.775)	
95% CI [2]	-0.45, 0.30	-1.08, -0.49	-1.46, 2.96	-2.50, 1.00	
Difference (95% CI) in CFB [2]		-0.72 (-1.13, -0.30)		-1.50 (-3.41, 0.41)	
p-value [3]		<0.001		0.109	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	54	102	4	9	
Mean (StdDev)	2.1 (1.26)	1.7 (1.36)	3.5 (0.58)	2.7 (1.12)	
Median	2.0	1.5	3.5	3.0	
Min, Max	0, 4	0, 4	3, 4	1, 4	
C7D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-0.29 (0.203)	-0.81 (0.156)	0.12 (1.015)	-1.38 (0.804)	
95% CI [2]	-0.69, 0.11	-1.12, -0.51	-2.17, 2.42	-3.19, 0.44	
Difference (95% CI) in CFB [2]		-0.53 (-0.97, -0.09)		-1.50 (-3.48, 0.48)	
Hedges'G (95% CI) in CFB		-0.34 (-0.69, -0.01)		-0.60 (-2.09, 0.62)	
p-value [3]		0.019		0.121	
					0.397

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	61	110	4	9	
Mean (StdDev)	2.2 (1.37)	2.4 (1.11)	3.5 (0.58)	3.1 (0.60)	
Median	3.0	2.0	3.5	3.0	
Min, Max	0, 4	0, 4	3, 4	2, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	61	111	4	8	
Mean (StdDev)	2.0 (1.19)	1.9 (1.20)	3.0 (0.82)	1.6 (1.41)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	2, 4	0, 3	
C2D1 CFB					
n	59	108	4	8	
LS Mean (StdErr) [2]	-0.09 (0.167)	-0.42 (0.133)	-1.44 (0.718)	-2.35 (0.566)	
95% CI [2]	-0.41, 0.24	-0.68, -0.16	-3.10, 0.22	-3.66, -1.05	
Difference (95% CI) in CFB [2]		-0.34 (-0.70, 0.03)		-0.91 (-2.35, 0.53)	
p-value [3]		0.070		0.183	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	59	101	4	8	
Mean (StdDev)	1.9 (1.38)	1.7 (1.09)	3.0 (1.15)	1.9 (1.46)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	2, 4	0, 4	
C3D1 CFB					
n	57	101	4	8	
LS Mean (StdErr) [2]	-0.21 (0.159)	-0.50 (0.125)	0.09 (0.934)	-1.03 (0.736)	
95% CI [2]	-0.52, 0.10	-0.75, -0.25	-2.07, 2.24	-2.73, 0.67	
Difference (95% CI) in CFB [2]		-0.29 (-0.64, 0.06)		-1.12 (-2.99, 0.76)	
p-value [3]		0.102		0.206	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	52	104	4	9	
Mean (StdDev)	1.9 (1.30)	1.7 (1.19)	3.8 (0.50)	2.0 (1.58)	
Median	2.0	2.0	4.0	2.0	
Min, Max	0, 4	0, 4	3, 4	0, 4	
C4D1 CFB					
n	50	102	4	9	
LS Mean (StdErr) [2]	-0.34 (0.195)	-0.66 (0.149)	1.40 (1.104)	-0.30 (0.875)	
95% CI [2]	-0.73, 0.04	-0.95, -0.37	-1.10, 3.90	-2.28, 1.68	
Difference (95% CI) in CFB [2]		-0.32 (-0.73, 0.10)		-1.70 (-3.85, 0.45)	
p-value [3]		0.135		0.108	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	55	100	4	9	
Mean (StdDev)	1.9 (1.30)	1.7 (1.21)	3.5 (0.58)	1.4 (1.59)	
Median	2.0	2.0	3.5	1.0	
Min, Max	0, 4	0, 4	3, 4	0, 4	
C5D1 CFB					
n	54	96	4	9	
LS Mean (StdErr) [2]	-0.14 (0.189)	-0.70 (0.149)	-0.85 (0.990)	-2.55 (0.784)	
95% CI [2]	-0.51, 0.24	-1.00, -0.41	-3.09, 1.39	-4.32, -0.78	
Difference (95% CI) in CFB [2]		-0.56 (-0.98, -0.15)		-1.70 (-3.63, 0.23)	
p-value [3]		0.008		0.078	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	102	4	9	
Mean (StdDev)	2.1 (1.32)	1.6 (1.20)	3.5 (0.58)	1.7 (1.73)	
Median	2.0	2.0	3.5	2.0	
Min, Max	0, 4	0, 4	3, 4	0, 4	
C6D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	0.10 (0.190)	-0.72 (0.149)	1.30 (1.054)	-0.60 (0.835)	
95% CI [2]	-0.28, 0.47	-1.01, -0.43	-1.08, 3.68	-2.49, 1.29	
Difference (95% CI) in CFB [2]		-0.82 (-1.24, -0.40)		-1.90 (-3.96, 0.16)	
p-value [3]		<0.001		0.066	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	54	102	4	9	
Mean (StdDev)	1.9 (1.33)	1.6 (1.26)	3.0 (0.82)	2.0 (1.58)	
Median	2.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	2, 4	0, 4	
C7D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-0.04 (0.191)	-0.66 (0.147)	-0.00 (1.093)	-1.00 (0.866)	
95% CI [2]	-0.42, 0.34	-0.95, -0.37	-2.47, 2.47	-2.96, 0.96	
Difference (95% CI) in CFB [2]		-0.62 (-1.03, -0.21)		-1.00 (-3.13, 1.13)	
Hedges'G (95% CI) in CFB		-0.43 (-0.78, -0.10)		-0.37 (-1.79, 0.88)	
p-value [3]		0.004		0.316	
					0.990

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	61	110	4	9	
Mean (StdDev)	1.6 (1.49)	1.8 (1.47)	3.5 (1.00)	2.7 (1.66)	
Median	1.0	2.0	4.0	3.0	
Min, Max	0, 4	0, 4	2, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	61	111	4	8	
Mean (StdDev)	1.7 (1.50)	1.5 (1.43)	3.3 (0.50)	2.5 (1.60)	
Median	1.0	1.0	3.0	3.0	
Min, Max	0, 4	0, 4	3, 4	0, 4	
C2D1 CFB					
n	59	108	4	8	
LS Mean (StdErr) [2]	-0.02 (0.156)	-0.34 (0.124)	-0.40 (1.228)	-0.37 (0.968)	
95% CI [2]	-0.32, 0.29	-0.58, -0.09	-3.23, 2.44	-2.60, 1.87	
Difference (95% CI) in CFB [2]		-0.32 (-0.66, 0.02)		0.03 (-2.43, 2.49)	
p-value [3]		0.065		0.979	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	59	101	4	8	
Mean (StdDev)	1.4 (1.55)	1.3 (1.38)	2.8 (1.26)	2.5 (1.41)	
Median	1.0	1.0	3.0	3.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C3D1 CFB					
n	57	101	4	8	
LS Mean (StdErr) [2]	-0.18 (0.161)	-0.47 (0.126)	-0.84 (1.218)	-0.22 (0.961)	
95% CI [2]	-0.50, 0.14	-0.72, -0.22	-3.65, 1.97	-2.44, 1.99	
Difference (95% CI) in CFB [2]		-0.29 (-0.64, 0.06)		0.62 (-1.83, 3.06)	
p-value [3]		0.104		0.576	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	52	104	4	9	
Mean (StdDev)	1.5 (1.32)	1.3 (1.35)	3.0 (0.82)	2.4 (1.59)	
Median	1.0	1.0	3.0	3.0	
Min, Max	0, 4	0, 4	2, 4	0, 4	
C4D1 CFB					
n	50	102	4	9	
LS Mean (StdErr) [2]	-0.17 (0.198)	-0.42 (0.151)	-0.45 (1.538)	-0.35 (1.219)	
95% CI [2]	-0.56, 0.22	-0.72, -0.12	-3.93, 3.03	-3.11, 2.41	
Difference (95% CI) in CFB [2]		-0.25 (-0.68, 0.17)		0.10 (-2.90, 3.10)	
p-value [3]		0.243		0.942	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	55	99	4	9	
Mean (StdDev)	1.3 (1.41)	1.2 (1.30)	2.8 (0.50)	2.7 (1.50)	
Median	1.0	1.0	3.0	3.0	
Min, Max	0, 4	0, 4	2, 3	0, 4	
C5D1 CFB					
n	54	95	4	9	
LS Mean (StdErr) [2]	-0.18 (0.197)	-0.54 (0.156)	-0.83 (1.422)	-0.22 (1.127)	
95% CI [2]	-0.56, 0.21	-0.84, -0.23	-4.04, 2.39	-2.77, 2.32	
Difference (95% CI) in CFB [2]		-0.36 (-0.80, 0.07)		0.60 (-2.17, 3.37)	
p-value [3]		0.103		0.636	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	102	4	9	
Mean (StdDev)	1.4 (1.41)	1.2 (1.37)	1.8 (1.26)	3.3 (0.71)	
Median	1.0	1.0	2.0	3.0	
Min, Max	0, 4	0, 4	0, 3	2, 4	
C6D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-0.19 (0.210)	-0.62 (0.164)	-1.08 (1.290)	1.03 (1.022)	
95% CI [2]	-0.60, 0.22	-0.95, -0.30	-3.99, 1.84	-1.29, 3.34	
Difference (95% CI) in CFB [2]		-0.43 (-0.89, 0.03)		2.10 (-0.42, 4.62)	
p-value [3]		0.066		0.092	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	54	102	4	9	
Mean (StdDev)	1.4 (1.42)	1.2 (1.37)	2.0 (1.41)	2.9 (1.27)	
Median	1.0	1.0	2.5	3.0	
Min, Max	0, 4	0, 4	0, 3	0, 4	
C7D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	0.05 (0.204)	-0.45 (0.157)	-1.65 (1.347)	0.05 (1.068)	
95% CI [2]	-0.35, 0.45	-0.76, -0.14	-4.70, 1.40	-2.37, 2.47	
Difference (95% CI) in CFB [2]		-0.50 (-0.94, -0.06)		1.70 (-0.93, 4.33)	
Hedges'G (95% CI) in CFB		-0.33 (-0.67, 0.01)		0.51 (-0.71, 1.98)	
p-value [3]		0.025		0.178	
					0.010

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	61	110	4	9	
Mean (StdDev)	2.0 (1.28)	2.3 (1.19)	3.8 (0.50)	2.8 (0.97)	
Median	2.0	2.0	4.0	3.0	
Min, Max	0, 4	0, 4	3, 4	1, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	61	111	4	8	
Mean (StdDev)	1.7 (1.22)	1.8 (1.18)	3.3 (0.50)	2.3 (0.89)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	3, 4	1, 4	
C2D1 CFB					
n	59	108	4	8	
LS Mean (StdErr) [2]	-0.32 (0.137)	-0.46 (0.109)	-0.24 (0.548)	-0.09 (0.432)	
95% CI [2]	-0.59, -0.05	-0.68, -0.25	-1.50, 1.03	-1.08, 0.91	
Difference (95% CI) in CFB [2]		-0.15 (-0.45, 0.15)		0.15 (-0.95, 1.25)	
p-value [3]		0.336		0.766	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	59	101	4	8	
Mean (StdDev)	1.8 (1.29)	1.6 (1.26)	3.0 (0.82)	2.3 (1.49)	
Median	2.0	2.0	3.0	2.5	
Min, Max	0, 4	0, 4	2, 4	0, 4	
C3D1 CFB					
n	57	101	4	8	
LS Mean (StdErr) [2]	-0.16 (0.154)	-0.73 (0.121)	-1.16 (0.729)	-0.78 (0.575)	
95% CI [2]	-0.47, 0.14	-0.97, -0.49	-2.84, 0.52	-2.11, 0.55	
Difference (95% CI) in CFB [2]		-0.56 (-0.90, -0.23)		0.38 (-1.08, 1.85)	
p-value [3]		0.001		0.564	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	52	104	4	9	
Mean (StdDev)	1.8 (1.15)	1.5 (1.15)	3.0 (0.00)	2.4 (1.33)	
Median	2.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	3, 3	0, 4	
C4D1 CFB					
n	50	102	4	9	
LS Mean (StdErr) [2]	-0.23 (0.158)	-0.77 (0.121)	-1.13 (0.504)	-0.62 (0.399)	
95% CI [2]	-0.54, 0.08	-1.00, -0.53	-2.26, 0.01	-1.53, 0.28	
Difference (95% CI) in CFB [2]		-0.54 (-0.88, -0.20)		0.50 (-0.48, 1.48)	
p-value [3]		0.002		0.280	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	55	100	4	9	
Mean (StdDev)	1.7 (1.18)	1.5 (1.18)	3.3 (0.50)	2.4 (1.51)	
Median	2.0	1.0	3.0	3.0	
Min, Max	0, 4	0, 4	3, 4	0, 4	
C5D1 CFB					
n	54	96	4	9	
LS Mean (StdErr) [2]	-0.35 (0.166)	-0.93 (0.131)	-0.90 (0.618)	-0.70 (0.490)	
95% CI [2]	-0.67, -0.02	-1.19, -0.68	-2.30, 0.50	-1.81, 0.41	
Difference (95% CI) in CFB [2]		-0.59 (-0.95, -0.22)		0.20 (-1.01, 1.41)	
p-value [3]		0.002		0.716	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	102	4	9	
Mean (StdDev)	2.0 (1.21)	1.4 (1.31)	3.3 (0.50)	2.9 (1.05)	
Median	2.0	1.0	3.0	3.0	
Min, Max	0, 4	0, 4	3, 4	1, 4	
C6D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-0.00 (0.173)	-0.88 (0.135)	-0.00 (0.423)	0.50 (0.335)	
95% CI [2]	-0.35, 0.34	-1.15, -0.61	-0.96, 0.96	-0.26, 1.26	
Difference (95% CI) in CFB [2]		-0.87 (-1.25, -0.49)		0.50 (-0.33, 1.33)	
p-value [3]		<0.0001		0.204	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	54	102	4	9	
Mean (StdDev)	1.8 (1.34)	1.4 (1.32)	3.5 (0.58)	2.2 (1.48)	
Median	2.0	1.0	3.5	3.0	
Min, Max	0, 4	0, 4	3, 4	0, 4	
C7D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-0.12 (0.170)	-0.78 (0.130)	-0.58 (0.591)	-0.98 (0.468)	
95% CI [2]	-0.46, 0.21	-1.04, -0.53	-1.91, 0.76	-2.03, 0.08	
Difference (95% CI) in CFB [2]		-0.66 (-1.03, -0.29)		-0.40 (-1.55, 0.75)	
Hedges'G (95% CI) in CFB		-0.52 (-0.87, -0.18)		-0.28 (-1.67, 0.99)	
p-value [3]		<0.001		0.453	
					0.645

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	61	110	4	9	
Mean (StdDev)	1.8 (1.34)	2.1 (1.29)	4.0 (0.00)	2.8 (1.30)	
Median	2.0	2.0	4.0	3.0	
Min, Max	0, 4	0, 4	4, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	61	111	4	8	
Mean (StdDev)	1.4 (1.17)	1.6 (1.27)	3.0 (0.82)	2.0 (1.41)	
Median	1.0	1.0	3.0	2.0	
Min, Max	0, 3	0, 4	2, 4	0, 4	
C2D1 CFB					
n	59	108	4	8	
LS Mean (StdErr) [2]	-0.37 (0.152)	-0.48 (0.121)	-0.56 (0.669)	-0.15 (0.528)	
95% CI [2]	-0.67, -0.07	-0.72, -0.24	-2.10, 0.98	-1.36, 1.07	
Difference (95% CI) in CFB [2]		-0.10 (-0.44, 0.23)		0.41 (-0.93, 1.75)	
p-value [3]		0.544		0.500	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	59	101	4	8	
Mean (StdDev)	1.5 (1.29)	1.4 (1.26)	2.8 (0.50)	1.9 (1.64)	
Median	1.0	1.0	3.0	2.5	
Min, Max	0, 4	0, 4	2, 3	0, 4	
C3D1 CFB					
n	57	101	4	8	
LS Mean (StdErr) [2]	-0.23 (0.157)	-0.63 (0.123)	-0.93 (0.751)	-0.69 (0.592)	
95% CI [2]	-0.54, 0.07	-0.87, -0.38	-2.66, 0.81	-2.06, 0.67	
Difference (95% CI) in CFB [2]		-0.39 (-0.73, -0.05)		0.24 (-1.27, 1.74)	
p-value [3]		0.025		0.728	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	52	104	4	9	
Mean (StdDev)	1.4 (1.06)	1.3 (1.22)	3.5 (0.58)	2.2 (1.48)	
Median	1.5	1.0	3.5	2.0	
Min, Max	0, 4	0, 4	3, 4	0, 4	
C4D1 CFB					
n	50	102	4	9	
LS Mean (StdErr) [2]	-0.43 (0.168)	-0.78 (0.128)	-0.18 (0.640)	-0.27 (0.507)	
95% CI [2]	-0.76, -0.10	-1.03, -0.52	-1.62, 1.27	-1.42, 0.87	
Difference (95% CI) in CFB [2]		-0.35 (-0.71, 0.01)		-0.10 (-1.35, 1.15)	
p-value [3]		0.059		0.860	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	55	100	4	9	
Mean (StdDev)	1.4 (1.29)	1.3 (1.15)	3.0 (0.00)	2.4 (1.59)	
Median	1.0	1.0	3.0	3.0	
Min, Max	0, 4	0, 4	3, 3	0, 4	
C5D1 CFB					
n	54	96	4	9	
LS Mean (StdErr) [2]	-0.27 (0.173)	-0.80 (0.137)	-0.83 (0.480)	-0.23 (0.380)	
95% CI [2]	-0.61, 0.08	-1.07, -0.53	-1.91, 0.26	-1.08, 0.63	
Difference (95% CI) in CFB [2]		-0.54 (-0.92, -0.16)		0.60 (-0.34, 1.54)	
p-value [3]		0.006		0.181	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	102	4	9	
Mean (StdDev)	1.5 (1.16)	1.3 (1.30)	3.8 (0.50)	2.6 (1.42)	
Median	1.0	1.0	4.0	3.0	
Min, Max	0, 4	0, 4	3, 4	0, 4	
C6D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-0.22 (0.175)	-0.84 (0.137)	0.93 (0.591)	0.53 (0.468)	
95% CI [2]	-0.57, 0.12	-1.11, -0.57	-0.41, 2.26	-0.53, 1.58	
Difference (95% CI) in CFB [2]		-0.62 (-1.00, -0.23)		-0.40 (-1.55, 0.75)	
p-value [3]		0.002		0.453	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	54	102	4	9	
Mean (StdDev)	1.4 (1.25)	1.2 (1.31)	3.5 (0.58)	2.0 (1.73)	
Median	1.0	1.0	3.5	3.0	
Min, Max	0, 4	0, 4	3, 4	0, 4	
C7D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-0.13 (0.178)	-0.68 (0.137)	-0.18 (0.685)	-0.78 (0.543)	
95% CI [2]	-0.48, 0.22	-0.95, -0.41	-1.72, 1.37	-2.00, 0.45	
Difference (95% CI) in CFB [2]		-0.55 (-0.94, -0.17)		-0.60 (-1.94, 0.74)	
Hedges'G (95% CI) in CFB		-0.41 (-0.76, -0.08)		-0.36 (-1.77, 0.90)	
p-value [3]		0.005		0.336	
					0.673

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	61	110	4	9	
Mean (StdDev)	3.0 (0.92)	2.9 (0.99)	3.8 (0.50)	3.0 (1.22)	
Median	3.0	3.0	4.0	3.0	
Min, Max	0, 4	0, 4	3, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	61	111	4	8	
Mean (StdDev)	2.5 (1.07)	2.5 (1.00)	3.5 (0.58)	2.3 (1.28)	
Median	2.0	3.0	3.5	2.5	
Min, Max	0, 4	0, 4	3, 4	0, 4	
C2D1 CFB					
n	59	108	4	8	
LS Mean (StdErr) [2]	-0.51 (0.136)	-0.43 (0.108)	-1.04 (0.502)	-1.49 (0.396)	
95% CI [2]	-0.78, -0.24	-0.64, -0.21	-2.20, 0.11	-2.40, -0.57	
Difference (95% CI) in CFB [2]		0.08 (-0.21, 0.38)		-0.44 (-1.45, 0.57)	
p-value [3]		0.581		0.342	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	59	101	4	8	
Mean (StdDev)	2.6 (1.05)	2.2 (1.10)	3.0 (1.15)	2.1 (1.55)	
Median	3.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	2, 4	0, 4	
C3D1 CFB					
n	57	101	4	8	
LS Mean (StdErr) [2]	-0.33 (0.142)	-0.59 (0.111)	-0.34 (0.970)	-0.72 (0.764)	
95% CI [2]	-0.61, -0.05	-0.81, -0.37	-2.57, 1.90	-2.48, 1.04	
Difference (95% CI) in CFB [2]		-0.26 (-0.57, 0.05)		-0.38 (-2.33, 1.56)	
p-value [3]		0.101		0.662	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	52	104	4	9	
Mean (StdDev)	2.3 (1.19)	2.3 (1.22)	3.8 (0.50)	2.4 (1.13)	
Median	2.0	2.0	4.0	2.0	
Min, Max	0, 4	0, 4	3, 4	1, 4	
C4D1 CFB					
n	50	102	4	9	
LS Mean (StdErr) [2]	-0.64 (0.162)	-0.52 (0.124)	0.38 (0.890)	-0.12 (0.705)	
95% CI [2]	-0.96, -0.32	-0.77, -0.28	-1.64, 2.39	-1.72, 1.47	
Difference (95% CI) in CFB [2]		0.12 (-0.23, 0.47)		-0.50 (-2.24, 1.24)	
p-value [3]		0.496		0.531	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	56	100	4	9	
Mean (StdDev)	2.5 (1.03)	2.1 (1.24)	3.5 (0.58)	1.4 (1.59)	
Median	2.0	2.0	3.5	1.0	
Min, Max	0, 4	0, 4	3, 4	0, 4	
C5D1 CFB					
n	55	96	4	9	
LS Mean (StdErr) [2]	-0.44 (0.164)	-0.84 (0.130)	-1.68 (1.089)	-2.78 (0.863)	
95% CI [2]	-0.76, -0.12	-1.09, -0.58	-4.14, 0.79	-4.73, -0.82	
Difference (95% CI) in CFB [2]		-0.40 (-0.76, -0.04)		-1.10 (-3.22, 1.02)	
p-value [3]		0.031		0.272	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	102	4	9	
Mean (StdDev)	2.5 (1.21)	2.2 (1.22)	3.5 (0.58)	1.8 (1.39)	
Median	2.0	2.0	3.5	2.0	
Min, Max	0, 4	0, 4	3, 4	0, 4	
C6D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-0.25 (0.178)	-0.58 (0.139)	-0.12 (0.985)	-1.13 (0.781)	
95% CI [2]	-0.60, 0.10	-0.86, -0.31	-2.35, 2.10	-2.89, 0.64	
Difference (95% CI) in CFB [2]		-0.33 (-0.72, 0.06)		-1.00 (-2.92, 0.92)	
p-value [3]		0.097		0.269	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	54	102	4	9	
Mean (StdDev)	2.5 (1.11)	2.1 (1.17)	3.3 (0.96)	2.3 (1.50)	
Median	3.0	2.0	3.5	2.0	
Min, Max	0, 4	0, 4	2, 4	0, 4	
C7D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-0.32 (0.164)	-0.67 (0.126)	-0.15 (0.990)	-0.45 (0.784)	
95% CI [2]	-0.64, 0.01	-0.92, -0.42	-2.39, 2.09	-2.22, 1.32	
Difference (95% CI) in CFB [2]		-0.36 (-0.71, -0.00)		-0.30 (-2.23, 1.63)	
Hedges'G (95% CI) in CFB		-0.29 (-0.63, 0.05)		-0.12 (-1.48, 1.17)	
p-value [3]		0.050		0.733	
					0.788

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	61	110	4	9	
Mean (StdDev)	2.4 (1.43)	2.4 (1.22)	3.0 (2.00)	2.4 (1.33)	
Median	3.0	2.0	4.0	2.0	
Min, Max	0, 4	0, 4	0, 4	1, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	61	111	4	8	
Mean (StdDev)	2.2 (1.23)	2.0 (1.37)	2.5 (1.29)	2.0 (1.31)	
Median	2.0	2.0	2.5	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C2D1 CFB					
n	59	108	4	8	
LS Mean (StdErr) [2]	-0.25 (0.155)	-0.50 (0.124)	-0.91 (0.897)	-0.53 (0.707)	
95% CI [2]	-0.56, 0.06	-0.75, -0.26	-2.98, 1.16	-2.16, 1.10	
Difference (95% CI) in CFB [2]		-0.25 (-0.60, 0.09)		0.38 (-1.42, 2.18)	
p-value [3]		0.142		0.637	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	59	101	4	8	
Mean (StdDev)	2.2 (1.20)	1.8 (1.30)	3.3 (0.96)	1.9 (1.25)	
Median	2.0	2.0	3.5	2.0	
Min, Max	0, 4	0, 4	2, 4	0, 3	
C3D1 CFB					
n	57	101	4	8	
LS Mean (StdErr) [2]	-0.24 (0.173)	-0.69 (0.135)	0.84 (0.817)	-0.28 (0.644)	
95% CI [2]	-0.58, 0.10	-0.96, -0.43	-1.05, 2.72	-1.77, 1.21	
Difference (95% CI) in CFB [2]		-0.46 (-0.83, -0.08)		-1.12 (-2.76, 0.52)	
p-value [3]		0.018		0.155	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	52	104	4	9	
Mean (StdDev)	2.0 (1.28)	1.8 (1.42)	2.8 (1.50)	2.3 (1.32)	
Median	2.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C4D1 CFB					
n	50	102	4	9	
LS Mean (StdErr) [2]	-0.41 (0.173)	-0.67 (0.132)	-0.30 (0.674)	-0.40 (0.534)	
95% CI [2]	-0.75, -0.07	-0.93, -0.41	-1.82, 1.22	-1.61, 0.81	
Difference (95% CI) in CFB [2]		-0.26 (-0.63, 0.11)		-0.10 (-1.41, 1.21)	
p-value [3]		0.166		0.867	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	56	100	4	9	
Mean (StdDev)	1.9 (1.42)	1.7 (1.42)	3.0 (2.00)	2.2 (1.86)	
Median	2.0	2.0	4.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	55	96	4	9	
LS Mean (StdErr) [2]	-0.41 (0.173)	-0.76 (0.137)	-0.48 (0.630)	-0.68 (0.499)	
95% CI [2]	-0.75, -0.07	-1.03, -0.49	-1.90, 0.95	-1.80, 0.45	
Difference (95% CI) in CFB [2]		-0.35 (-0.74, 0.03)		-0.20 (-1.43, 1.03)	
p-value [3]		0.069		0.721	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	102	4	9	
Mean (StdDev)	2.2 (1.26)	1.6 (1.36)	2.8 (1.89)	1.9 (1.69)	
Median	2.0	1.5	3.5	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-0.11 (0.183)	-0.82 (0.143)	-0.58 (0.332)	-0.98 (0.263)	
95% CI [2]	-0.47, 0.26	-1.11, -0.54	-1.33, 0.18	-1.57, -0.38	
Difference (95% CI) in CFB [2]		-0.72 (-1.12, -0.32)		-0.40 (-1.05, 0.25)	
p-value [3]		<0.001		0.196	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	54	102	4	9	
Mean (StdDev)	2.0 (1.40)	1.5 (1.41)	2.8 (1.89)	1.9 (1.54)	
Median	2.0	1.0	3.5	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-0.33 (0.190)	-0.82 (0.146)	0.05 (0.394)	-0.35 (0.312)	
95% CI [2]	-0.71, 0.05	-1.11, -0.53	-0.84, 0.94	-1.06, 0.36	
Difference (95% CI) in CFB [2]		-0.49 (-0.90, -0.08)		-0.40 (-1.17, 0.37)	
Hedges'G (95% CI) in CFB		-0.34 (-0.69, -0.01)		-0.41 (-1.85, 0.83)	
p-value [3]		0.020		0.269	
					0.856

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	61	110	4	9	
Mean (StdDev)	2.7 (1.14)	3.0 (0.99)	3.8 (0.50)	3.2 (0.67)	
Median	3.0	3.0	4.0	3.0	
Min, Max	0, 4	0, 4	3, 4	2, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	61	111	4	8	
Mean (StdDev)	2.1 (1.11)	2.3 (1.25)	3.5 (0.58)	2.8 (0.89)	
Median	2.0	2.0	3.5	2.5	
Min, Max	0, 4	0, 4	3, 4	2, 4	
C2D1 CFB					
n	59	108	4	8	
LS Mean (StdErr) [2]	-0.60 (0.147)	-0.74 (0.117)	-0.04 (0.623)	-0.49 (0.491)	
95% CI [2]	-0.89, -0.31	-0.97, -0.51	-1.48, 1.39	-1.62, 0.65	
Difference (95% CI) in CFB [2]		-0.14 (-0.46, 0.18)		-0.44 (-1.69, 0.81)	
p-value [3]		0.399		0.439	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	59	101	4	8	
Mean (StdDev)	2.4 (1.23)	2.0 (1.23)	2.8 (0.96)	2.8 (0.89)	
Median	2.0	2.0	2.5	3.0	
Min, Max	0, 4	0, 4	2, 4	1, 4	
C3D1 CFB					
n	57	101	4	8	
LS Mean (StdErr) [2]	-0.36 (0.162)	-0.97 (0.127)	-0.18 (0.704)	0.06 (0.555)	
95% CI [2]	-0.68, -0.04	-1.22, -0.72	-1.80, 1.45	-1.22, 1.34	
Difference (95% CI) in CFB [2]		-0.60 (-0.96, -0.25)		0.24 (-1.18, 1.65)	
p-value [3]		<0.001		0.711	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	52	104	4	9	
Mean (StdDev)	2.4 (1.16)	2.0 (1.24)	3.8 (0.50)	2.4 (1.24)	
Median	2.0	2.0	4.0	3.0	
Min, Max	0, 4	0, 4	3, 4	0, 4	
C4D1 CFB					
n	50	102	4	9	
LS Mean (StdErr) [2]	-0.38 (0.169)	-0.96 (0.129)	-0.15 (0.749)	-0.95 (0.594)	
95% CI [2]	-0.72, -0.05	-1.21, -0.70	-1.84, 1.54	-2.29, 0.39	
Difference (95% CI) in CFB [2]		-0.57 (-0.93, -0.21)		-0.80 (-2.26, 0.66)	
p-value [3]		0.002		0.247	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	56	99	4	9	
Mean (StdDev)	2.2 (1.17)	2.0 (1.18)	3.5 (0.58)	2.4 (1.42)	
Median	2.0	2.0	3.5	2.0	
Min, Max	0, 4	0, 4	3, 4	0, 4	
C5D1 CFB					
n	55	95	4	9	
LS Mean (StdErr) [2]	-0.46 (0.163)	-1.02 (0.129)	-0.43 (0.841)	-1.03 (0.667)	
95% CI [2]	-0.78, -0.14	-1.28, -0.76	-2.33, 1.48	-2.53, 0.48	
Difference (95% CI) in CFB [2]		-0.56 (-0.92, -0.20)		-0.60 (-2.24, 1.04)	
p-value [3]		0.002		0.430	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	102	4	9	
Mean (StdDev)	2.4 (1.14)	1.8 (1.32)	3.8 (0.50)	2.7 (1.00)	
Median	2.0	2.0	4.0	3.0	
Min, Max	0, 4	0, 4	3, 4	1, 4	
C6D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-0.34 (0.173)	-1.15 (0.135)	0.23 (0.630)	-0.58 (0.499)	
95% CI [2]	-0.68, 0.00	-1.42, -0.89	-1.20, 1.65	-1.70, 0.55	
Difference (95% CI) in CFB [2]		-0.81 (-1.19, -0.43)		-0.80 (-2.03, 0.43)	
p-value [3]		<0.0001		0.175	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	54	102	4	9	
Mean (StdDev)	2.2 (1.34)	1.9 (1.35)	3.3 (0.50)	2.3 (1.12)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	3, 4	0, 4	
C7D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-0.37 (0.174)	-0.96 (0.134)	-0.05 (0.796)	-0.65 (0.630)	
95% CI [2]	-0.71, -0.02	-1.23, -0.70	-1.85, 1.75	-2.08, 0.78	
Difference (95% CI) in CFB [2]		-0.60 (-0.97, -0.22)		-0.60 (-2.15, 0.95)	
Hedges'G (95% CI) in CFB		-0.46 (-0.80, -0.12)		-0.31 (-1.71, 0.95)	
p-value [3]		0.002		0.405	
					0.739

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	61	110	4	9	
Mean (StdDev)	3.0 (0.92)	3.1 (0.96)	4.0 (0.00)	3.4 (0.53)	
Median	3.0	3.0	4.0	3.0	
Min, Max	0, 4	0, 4	4, 4	3, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	61	111	4	8	
Mean (StdDev)	2.6 (0.99)	2.3 (1.07)	3.5 (0.58)	3.1 (0.83)	
Median	3.0	2.0	3.5	3.0	
Min, Max	0, 4	0, 4	3, 4	2, 4	
C2D1 CFB					
n	59	108	4	8	
LS Mean (StdErr) [2]	-0.43 (0.133)	-0.81 (0.106)	-0.24 (0.548)	-0.09 (0.432)	
95% CI [2]	-0.70, -0.17	-1.02, -0.60	-1.50, 1.03	-1.08, 0.91	
Difference (95% CI) in CFB [2]		-0.38 (-0.67, -0.09)		0.15 (-0.95, 1.25)	
p-value [3]		0.012		0.766	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	59	101	4	8	
Mean (StdDev)	2.5 (1.10)	2.1 (1.17)	3.0 (0.82)	2.6 (1.19)	
Median	3.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	2, 4	1, 4	
C3D1 CFB					
n	57	101	4	8	
LS Mean (StdErr) [2]	-0.52 (0.156)	-1.00 (0.122)	-0.56 (0.617)	-0.65 (0.486)	
95% CI [2]	-0.83, -0.21	-1.24, -0.76	-1.98, 0.86	-1.77, 0.47	
Difference (95% CI) in CFB [2]		-0.48 (-0.82, -0.14)		-0.09 (-1.32, 1.15)	
p-value [3]		0.006		0.873	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	52	104	4	9	
Mean (StdDev)	2.4 (1.14)	2.0 (1.14)	3.3 (0.96)	2.9 (0.93)	
Median	2.0	2.0	3.5	3.0	
Min, Max	0, 4	0, 4	2, 4	1, 4	
C4D1 CFB					
n	50	102	4	9	
LS Mean (StdErr) [2]	-0.64 (0.158)	-1.14 (0.121)	-0.45 (0.628)	-0.35 (0.497)	
95% CI [2]	-0.95, -0.33	-1.38, -0.90	-1.87, 0.97	-1.48, 0.78	
Difference (95% CI) in CFB [2]		-0.50 (-0.83, -0.16)		0.10 (-1.13, 1.33)	
p-value [3]		0.004		0.858	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	56	100	4	9	
Mean (StdDev)	2.4 (1.29)	2.1 (1.16)	3.3 (0.96)	3.1 (1.17)	
Median	3.0	2.0	3.5	4.0	
Min, Max	0, 4	0, 4	2, 4	1, 4	
C5D1 CFB					
n	55	96	4	9	
LS Mean (StdErr) [2]	-0.50 (0.170)	-1.03 (0.135)	-1.13 (0.702)	-0.62 (0.556)	
95% CI [2]	-0.83, -0.16	-1.29, -0.76	-2.71, 0.46	-1.88, 0.63	
Difference (95% CI) in CFB [2]		-0.53 (-0.91, -0.16)		0.50 (-0.87, 1.87)	
p-value [3]		0.006		0.430	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	102	4	9	
Mean (StdDev)	2.5 (1.14)	2.0 (1.29)	3.5 (1.00)	2.7 (1.00)	
Median	3.0	2.0	4.0	3.0	
Min, Max	0, 4	0, 4	2, 4	1, 4	
C6D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-0.43 (0.179)	-1.15 (0.140)	-0.08 (0.767)	-0.48 (0.608)	
95% CI [2]	-0.78, -0.07	-1.43, -0.87	-1.81, 1.66	-1.85, 0.90	
Difference (95% CI) in CFB [2]		-0.72 (-1.11, -0.33)		-0.40 (-1.90, 1.10)	
p-value [3]		<0.001		0.560	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	54	102	4	9	
Mean (StdDev)	2.4 (1.35)	1.9 (1.26)	3.0 (0.82)	2.6 (1.33)	
Median	3.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	2, 4	0, 4	
C7D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-0.47 (0.181)	-1.09 (0.139)	-0.50 (0.847)	-0.50 (0.671)	
95% CI [2]	-0.83, -0.12	-1.37, -0.82	-2.42, 1.42	-2.02, 1.02	
Difference (95% CI) in CFB [2]		-0.62 (-1.01, -0.23)		0.00 (-1.65, 1.65)	
Hedges'G (95% CI) in CFB		-0.45 (-0.80, -0.12)		0.00 (-1.32, 1.32)	
p-value [3]		0.002		>0.999	
					0.289

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	61	110	4	9	
Mean (StdDev)	2.2 (1.45)	1.8 (1.49)	3.3 (0.96)	2.6 (1.33)	
Median	3.0	2.0	3.5	2.0	
Min, Max	0, 4	0, 4	2, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	61	111	4	8	
Mean (StdDev)	2.0 (1.45)	1.5 (1.45)	2.0 (1.15)	1.6 (1.06)	
Median	2.0	1.0	2.0	1.5	
Min, Max	0, 4	0, 4	1, 3	0, 3	
C2D1 CFB					
n	59	108	4	8	
LS Mean (StdErr) [2]	0.00 (0.168)	-0.14 (0.134)	-0.75 (0.940)	-0.25 (0.741)	
95% CI [2]	-0.33, 0.33	-0.41, 0.12	-2.92, 1.42	-1.96, 1.46	
Difference (95% CI) in CFB [2]		-0.15 (-0.51, 0.22)		0.50 (-1.39, 2.39)	
p-value [3]		0.437		0.558	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	59	101	4	8	
Mean (StdDev)	2.0 (1.41)	1.4 (1.42)	2.5 (1.00)	1.1 (1.55)	
Median	2.0	1.0	3.0	0.5	
Min, Max	0, 4	0, 4	1, 3	0, 4	
C3D1 CFB					
n	57	101	4	8	
LS Mean (StdErr) [2]	-0.05 (0.188)	-0.29 (0.147)	-0.07 (0.986)	-0.81 (0.777)	
95% CI [2]	-0.42, 0.32	-0.59, -0.00	-2.35, 2.20	-2.60, 0.98	
Difference (95% CI) in CFB [2]		-0.24 (-0.65, 0.17)		-0.74 (-2.71, 1.24)	
p-value [3]		0.247		0.416	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	52	104	4	9	
Mean (StdDev)	1.9 (1.31)	1.5 (1.39)	2.0 (0.82)	1.8 (1.86)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	1, 3	0, 4	
C4D1 CFB					
n	50	102	4	9	
LS Mean (StdErr) [2]	-0.16 (0.181)	-0.20 (0.139)	-0.90 (1.048)	-0.70 (0.831)	
95% CI [2]	-0.52, 0.20	-0.48, 0.07	-3.27, 1.47	-2.58, 1.18	
Difference (95% CI) in CFB [2]		-0.04 (-0.43, 0.35)		0.20 (-1.85, 2.25)	
p-value [3]		0.840		0.830	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	56	100	4	9	
Mean (StdDev)	1.8 (1.36)	1.4 (1.36)	2.8 (0.96)	1.8 (1.92)	
Median	2.0	1.0	2.5	1.0	
Min, Max	0, 4	0, 4	2, 4	0, 4	
C5D1 CFB					
n	55	96	4	9	
LS Mean (StdErr) [2]	-0.22 (0.199)	-0.30 (0.157)	-0.13 (1.072)	-0.63 (0.850)	
95% CI [2]	-0.61, 0.17	-0.61, 0.01	-2.55, 2.30	-2.55, 1.30	
Difference (95% CI) in CFB [2]		-0.08 (-0.51, 0.36)		-0.50 (-2.59, 1.59)	
p-value [3]		0.734		0.602	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	102	4	9	
Mean (StdDev)	1.9 (1.44)	1.4 (1.35)	2.0 (1.83)	1.4 (1.59)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-0.22 (0.205)	-0.38 (0.160)	-0.58 (1.032)	-0.48 (0.818)	
95% CI [2]	-0.63, 0.18	-0.70, -0.07	-2.91, 1.76	-2.33, 1.38	
Difference (95% CI) in CFB [2]		-0.16 (-0.61, 0.29)		0.10 (-1.91, 2.11)	
p-value [3]		0.482		0.913	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	54	102	4	9	
Mean (StdDev)	1.9 (1.50)	1.2 (1.29)	2.8 (1.26)	1.8 (1.92)	
Median	2.0	1.0	3.0	1.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C7D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	0.04 (0.208)	-0.31 (0.160)	-0.13 (0.890)	-0.63 (0.705)	
95% CI [2]	-0.37, 0.45	-0.62, 0.01	-2.14, 1.89	-2.22, 0.97	
Difference (95% CI) in CFB [2]		-0.35 (-0.80, 0.10)		-0.50 (-2.24, 1.24)	
Hedges'G (95% CI) in CFB		-0.22 (-0.56, 0.11)		-0.23 (-1.61, 1.05)	
p-value [3]		0.130		0.531	
					0.870

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	61	110	4	9	
Mean (StdDev)	1.8 (1.27)	1.7 (1.30)	1.3 (0.50)	2.1 (1.62)	
Median	2.0	2.0	1.0	3.0	
Min, Max	0, 4	0, 4	1, 2	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	61	111	4	8	
Mean (StdDev)	1.5 (1.12)	1.4 (1.24)	1.5 (0.58)	1.8 (1.58)	
Median	1.0	1.0	1.5	2.0	
Min, Max	0, 4	0, 4	1, 2	0, 4	
C2D1 CFB					
n	59	108	4	8	
LS Mean (StdErr) [2]	-0.33 (0.126)	-0.45 (0.100)	0.34 (0.510)	-0.28 (0.402)	
95% CI [2]	-0.58, -0.08	-0.64, -0.25	-0.84, 1.51	-1.21, 0.65	
Difference (95% CI) in CFB [2]		-0.12 (-0.39, 0.16)		-0.62 (-1.64, 0.41)	
p-value [3]		0.405		0.201	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	59	101	4	8	
Mean (StdDev)	1.6 (1.18)	1.1 (1.16)	1.5 (1.00)	1.8 (1.75)	
Median	1.0	1.0	1.0	1.5	
Min, Max	0, 4	0, 4	1, 3	0, 4	
C3D1 CFB					
n	57	101	4	8	
LS Mean (StdErr) [2]	-0.28 (0.167)	-0.69 (0.131)	0.28 (0.562)	-0.43 (0.443)	
95% CI [2]	-0.61, 0.05	-0.95, -0.43	-1.02, 1.58	-1.45, 0.60	
Difference (95% CI) in CFB [2]		-0.42 (-0.78, -0.05)		-0.71 (-1.83, 0.42)	
p-value [3]		0.026		0.187	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	52	104	4	9	
Mean (StdDev)	1.6 (1.18)	1.0 (1.16)	1.5 (1.00)	1.7 (1.50)	
Median	2.0	1.0	1.0	2.0	
Min, Max	0, 4	0, 4	1, 3	0, 4	
C4D1 CFB					
n	50	102	4	9	
LS Mean (StdErr) [2]	-0.27 (0.182)	-0.74 (0.139)	0.48 (0.527)	-0.33 (0.418)	
95% CI [2]	-0.63, 0.08	-1.02, -0.47	-0.72, 1.67	-1.27, 0.62	
Difference (95% CI) in CFB [2]		-0.47 (-0.86, -0.08)		-0.80 (-1.83, 0.23)	
p-value [3]		0.019		0.112	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	56	100	4	9	
Mean (StdDev)	1.5 (1.16)	1.0 (1.17)	1.5 (1.00)	1.8 (1.56)	
Median	1.0	1.0	1.0	2.0	
Min, Max	0, 4	0, 4	1, 3	0, 4	
C5D1 CFB					
n	55	96	4	9	
LS Mean (StdErr) [2]	-0.38 (0.163)	-0.83 (0.129)	0.35 (0.665)	-0.45 (0.527)	
95% CI [2]	-0.70, -0.06	-1.08, -0.57	-1.15, 1.85	-1.64, 0.74	
Difference (95% CI) in CFB [2]		-0.45 (-0.80, -0.09)		-0.80 (-2.10, 0.50)	
p-value [3]		0.015		0.196	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	102	4	9	
Mean (StdDev)	1.6 (1.14)	1.1 (1.16)	1.5 (1.73)	1.7 (1.50)	
Median	2.0	1.0	1.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-0.31 (0.161)	-0.73 (0.126)	0.48 (0.935)	-0.33 (0.741)	
95% CI [2]	-0.63, 0.01	-0.98, -0.48	-1.64, 2.59	-2.00, 1.35	
Difference (95% CI) in CFB [2]		-0.42 (-0.77, -0.07)		-0.80 (-2.63, 1.03)	
p-value [3]		0.021		0.347	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	54	102	4	9	
Mean (StdDev)	1.3 (1.13)	1.0 (1.13)	1.5 (1.00)	1.7 (1.50)	
Median	1.0	1.0	1.0	2.0	
Min, Max	0, 4	0, 4	1, 3	0, 4	
C7D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-0.41 (0.161)	-0.67 (0.124)	0.43 (0.685)	-0.48 (0.543)	
95% CI [2]	-0.72, -0.09	-0.91, -0.42	-1.12, 1.97	-1.70, 0.75	
Difference (95% CI) in CFB [2]		-0.26 (-0.61, 0.09)		-0.90 (-2.24, 0.44)	
Hedges'G (95% CI) in CFB		-0.22 (-0.56, 0.12)		-0.54 (-2.01, 0.69)	
p-value [3]		0.139		0.162	
					0.589

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	61	110	4	9	
Mean (StdDev)	1.2 (1.26)	1.4 (1.43)	1.5 (1.73)	2.3 (1.80)	
Median	1.0	1.0	1.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	61	111	4	8	
Mean (StdDev)	1.2 (1.33)	1.2 (1.30)	1.5 (1.73)	2.3 (1.91)	
Median	1.0	1.0	1.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	59	108	4	8	
LS Mean (StdErr) [2]	0.05 (0.149)	-0.12 (0.119)	-0.03 (0.424)	0.18 (0.335)	
95% CI [2]	-0.25, 0.34	-0.36, 0.11	-1.01, 0.95	-0.59, 0.95	
Difference (95% CI) in CFB [2]		-0.17 (-0.50, 0.16)		0.21 (-0.65, 1.06)	
p-value [3]		0.302		0.592	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	59	101	4	8	
Mean (StdDev)	1.0 (1.20)	1.0 (1.22)	1.3 (1.26)	1.4 (1.60)	
Median	1.0	0.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 3	0, 4	
C3D1 CFB					
n	57	101	4	8	
LS Mean (StdErr) [2]	-0.08 (0.169)	-0.31 (0.132)	0.19 (0.808)	-0.40 (0.637)	
95% CI [2]	-0.41, 0.25	-0.57, -0.05	-1.67, 2.05	-1.87, 1.07	
Difference (95% CI) in CFB [2]		-0.23 (-0.60, 0.14)		-0.59 (-2.21, 1.03)	
p-value [3]		0.220		0.427	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	52	104	4	9	
Mean (StdDev)	1.3 (1.26)	1.0 (1.16)	2.0 (1.41)	1.9 (1.83)	
Median	1.0	1.0	1.5	1.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C4D1 CFB					
n	50	102	4	9	
LS Mean (StdErr) [2]	-0.02 (0.182)	-0.46 (0.139)	0.65 (0.665)	-0.55 (0.527)	
95% CI [2]	-0.38, 0.34	-0.73, -0.18	-0.85, 2.15	-1.74, 0.64	
Difference (95% CI) in CFB [2]		-0.43 (-0.82, -0.04)		-1.20 (-2.50, 0.10)	
p-value [3]		0.029		0.066	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	56	100	4	9	
Mean (StdDev)	1.2 (1.23)	0.8 (1.14)	1.5 (1.73)	2.0 (1.73)	
Median	1.0	0.0	1.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	55	96	4	9	
LS Mean (StdErr) [2]	-0.04 (0.167)	-0.55 (0.132)	0.12 (0.441)	-0.38 (0.349)	
95% CI [2]	-0.37, 0.29	-0.81, -0.29	-0.87, 1.12	-1.16, 0.41	
Difference (95% CI) in CFB [2]		-0.51 (-0.88, -0.14)		-0.50 (-1.36, 0.36)	
p-value [3]		0.007		0.221	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	102	4	9	
Mean (StdDev)	1.2 (1.22)	0.9 (1.13)	1.5 (1.73)	1.8 (1.72)	
Median	1.0	0.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-0.04 (0.173)	-0.54 (0.135)	0.27 (0.581)	-0.43 (0.460)	
95% CI [2]	-0.39, 0.30	-0.80, -0.27	-1.04, 1.59	-1.47, 0.62	
Difference (95% CI) in CFB [2]		-0.49 (-0.87, -0.11)		-0.70 (-1.83, 0.43)	
p-value [3]		0.012		0.196	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	54	102	4	9	
Mean (StdDev)	1.1 (1.21)	0.9 (1.20)	1.5 (1.00)	1.7 (1.66)	
Median	1.0	0.0	1.0	2.0	
Min, Max	0, 4	0, 4	1, 3	0, 4	
C7D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-0.00 (0.169)	-0.40 (0.130)	0.35 (0.749)	-0.45 (0.594)	
95% CI [2]	-0.33, 0.33	-0.66, -0.14	-1.34, 2.04	-1.79, 0.89	
Difference (95% CI) in CFB [2]		-0.40 (-0.76, -0.03)		-0.80 (-2.26, 0.66)	
Hedges'G (95% CI) in CFB		-0.31 (-0.66, 0.02)		-0.44 (-1.87, 0.81)	
p-value [3]		0.032		0.247	
					0.789

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	61	110	4	9	
Mean (StdDev)	2.0 (1.12)	2.0 (1.28)	1.8 (1.26)	1.9 (1.54)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 3	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	61	111	4	8	
Mean (StdDev)	1.5 (1.27)	1.5 (1.26)	2.0 (0.82)	1.1 (1.36)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	1, 3	0, 4	
C2D1 CFB					
n	59	108	4	8	
LS Mean (StdErr) [2]	-0.54 (0.154)	-0.59 (0.123)	0.51 (0.660)	-0.34 (0.521)	
95% CI [2]	-0.85, -0.24	-0.84, -0.35	-1.01, 2.04	-1.54, 0.86	
Difference (95% CI) in CFB [2]		-0.05 (-0.39, 0.29)		-0.85 (-2.18, 0.47)	
p-value [3]		0.763		0.176	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	59	101	4	8	
Mean (StdDev)	1.5 (1.15)	1.4 (1.12)	1.8 (0.50)	1.1 (1.36)	
Median	2.0	1.0	2.0	0.5	
Min, Max	0, 4	0, 4	1, 2	0, 3	
C3D1 CFB					
n	57	101	4	8	
LS Mean (StdErr) [2]	-0.42 (0.150)	-0.62 (0.118)	0.18 (0.751)	-0.56 (0.592)	
95% CI [2]	-0.72, -0.13	-0.85, -0.39	-1.56, 1.91	-1.92, 0.81	
Difference (95% CI) in CFB [2]		-0.20 (-0.53, 0.13)		-0.74 (-2.24, 0.77)	
p-value [3]		0.235		0.293	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	52	104	4	9	
Mean (StdDev)	1.5 (1.28)	1.4 (1.20)	2.0 (0.82)	1.6 (1.51)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	1, 3	0, 4	
C4D1 CFB					
n	50	102	4	9	
LS Mean (StdErr) [2]	-0.39 (0.184)	-0.70 (0.140)	0.45 (0.524)	-0.15 (0.415)	
95% CI [2]	-0.76, -0.03	-0.98, -0.42	-0.74, 1.64	-1.09, 0.79	
Difference (95% CI) in CFB [2]		-0.31 (-0.70, 0.09)		-0.60 (-1.62, 0.42)	
p-value [3]		0.125		0.217	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	56	100	4	9	
Mean (StdDev)	1.4 (1.32)	1.1 (1.13)	1.8 (1.26)	1.4 (1.74)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 3	0, 4	
C5D1 CFB					
n	55	96	4	9	
LS Mean (StdErr) [2]	-0.40 (0.170)	-0.83 (0.134)	0.20 (0.674)	-0.40 (0.534)	
95% CI [2]	-0.73, -0.06	-1.09, -0.56	-1.32, 1.72	-1.61, 0.81	
Difference (95% CI) in CFB [2]		-0.43 (-0.80, -0.06)		-0.60 (-1.91, 0.71)	
p-value [3]		0.024		0.329	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	102	4	9	
Mean (StdDev)	1.5 (1.31)	1.0 (1.09)	2.3 (0.50)	1.3 (1.58)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	2, 3	0, 4	
C6D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-0.37 (0.176)	-1.10 (0.138)	0.72 (0.676)	-0.58 (0.536)	
95% CI [2]	-0.71, -0.02	-1.37, -0.83	-0.80, 2.25	-1.79, 0.64	
Difference (95% CI) in CFB [2]		-0.73 (-1.12, -0.35)		-1.30 (-2.62, 0.02)	
p-value [3]		<0.001		0.053	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	54	102	4	9	
Mean (StdDev)	1.5 (1.37)	1.1 (1.25)	2.3 (0.96)	1.2 (1.30)	
Median	2.0	1.0	2.5	1.0	
Min, Max	0, 4	0, 4	1, 3	0, 4	
C7D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-0.31 (0.199)	-0.77 (0.153)	0.80 (0.901)	-0.60 (0.714)	
95% CI [2]	-0.70, 0.08	-1.07, -0.46	-1.24, 2.84	-2.22, 1.02	
Difference (95% CI) in CFB [2]		-0.46 (-0.89, -0.02)		-1.40 (-3.16, 0.36)	
Hedges'G (95% CI) in CFB		-0.30 (-0.65, 0.03)		-0.63 (-2.13, 0.58)	
p-value [3]		0.038		0.105	
					0.394

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	61	110	4	9	
Mean (StdDev)	2.3 (1.03)	2.3 (1.18)	2.3 (0.50)	2.6 (1.42)	
Median	2.0	2.0	2.0	3.0	
Min, Max	0, 4	0, 4	2, 3	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	61	111	4	8	
Mean (StdDev)	1.8 (1.15)	1.6 (1.29)	1.8 (0.96)	2.3 (1.28)	
Median	2.0	2.0	1.5	2.5	
Min, Max	0, 4	0, 4	1, 3	0, 4	
C2D1 CFB					
n	59	108	4	8	
LS Mean (StdErr) [2]	-0.46 (0.149)	-0.64 (0.118)	-0.41 (1.037)	-0.03 (0.818)	
95% CI [2]	-0.76, -0.17	-0.87, -0.40	-2.80, 1.98	-1.92, 1.86	
Difference (95% CI) in CFB [2]		-0.17 (-0.50, 0.15)		0.38 (-1.70, 2.46)	
p-value [3]		0.299		0.683	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	59	101	4	8	
Mean (StdDev)	1.9 (1.14)	1.4 (1.11)	1.3 (0.50)	1.9 (1.36)	
Median	2.0	1.0	1.0	1.5	
Min, Max	0, 4	0, 4	1, 2	0, 4	
C3D1 CFB					
n	57	101	4	8	
LS Mean (StdErr) [2]	-0.40 (0.161)	-0.87 (0.126)	-0.71 (0.966)	-0.26 (0.761)	
95% CI [2]	-0.72, -0.08	-1.12, -0.62	-2.93, 1.52	-2.02, 1.49	
Difference (95% CI) in CFB [2]		-0.47 (-0.83, -0.12)		0.44 (-1.50, 2.38)	
p-value [3]		0.009		0.614	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	52	103	4	9	
Mean (StdDev)	1.8 (1.14)	1.4 (1.23)	2.3 (0.96)	2.2 (1.39)	
Median	2.0	1.0	2.5	2.0	
Min, Max	0, 4	0, 4	1, 3	0, 4	
C4D1 CFB					
n	50	101	4	9	
LS Mean (StdErr) [2]	-0.61 (0.171)	-1.02 (0.131)	0.75 (1.246)	0.25 (0.987)	
95% CI [2]	-0.95, -0.27	-1.27, -0.76	-2.07, 3.57	-1.98, 2.48	
Difference (95% CI) in CFB [2]		-0.41 (-0.77, -0.04)		-0.50 (-2.93, 1.93)	
p-value [3]		0.029		0.653	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	56	100	4	9	
Mean (StdDev)	1.7 (1.35)	1.3 (1.21)	1.3 (0.96)	2.2 (1.20)	
Median	2.0	1.0	1.5	2.0	
Min, Max	0, 4	0, 4	0, 2	0, 4	
C5D1 CFB					
n	55	96	4	9	
LS Mean (StdErr) [2]	-0.63 (0.180)	-1.06 (0.142)	-0.78 (1.027)	-0.07 (0.814)	
95% CI [2]	-0.98, -0.27	-1.34, -0.78	-3.10, 1.55	-1.92, 1.77	
Difference (95% CI) in CFB [2]		-0.44 (-0.83, -0.04)		0.70 (-1.30, 2.70)	
p-value [3]		0.031		0.450	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	102	4	9	
Mean (StdDev)	1.7 (1.24)	1.3 (1.24)	2.0 (1.41)	1.9 (1.36)	
Median	2.0	1.0	1.5	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C6D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-0.57 (0.179)	-1.09 (0.140)	1.07 (0.909)	-0.03 (0.721)	
95% CI [2]	-0.92, -0.22	-1.37, -0.81	-0.98, 3.13	-1.66, 1.61	
Difference (95% CI) in CFB [2]		-0.52 (-0.91, -0.12)		-1.10 (-2.87, 0.67)	
p-value [3]		0.010		0.194	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	54	102	4	9	
Mean (StdDev)	1.6 (1.25)	1.3 (1.23)	1.8 (0.96)	2.0 (1.41)	
Median	1.0	1.0	1.5	2.0	
Min, Max	0, 4	0, 4	1, 3	0, 4	
C7D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-0.58 (0.185)	-0.88 (0.143)	0.25 (0.914)	-0.25 (0.725)	
95% CI [2]	-0.94, -0.21	-1.16, -0.59	-1.82, 2.32	-1.89, 1.39	
Difference (95% CI) in CFB [2]		-0.30 (-0.70, 0.10)		-0.50 (-2.28, 1.28)	
Hedges'G (95% CI) in CFB		-0.21 (-0.56, 0.12)		-0.22 (-1.60, 1.05)	
p-value [3]		0.142		0.542	
					0.709

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	61	110	4	9	
Mean (StdDev)	2.6 (1.15)	2.7 (1.07)	3.5 (0.58)	2.9 (1.36)	
Median	3.0	3.0	3.5	3.0	
Min, Max	0, 4	0, 4	3, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	61	111	4	8	
Mean (StdDev)	2.2 (1.12)	2.2 (1.20)	3.5 (0.58)	2.5 (1.07)	
Median	2.0	2.0	3.5	3.0	
Min, Max	0, 4	0, 4	3, 4	1, 4	
C2D1 CFB					
n	59	108	4	8	
LS Mean (StdErr) [2]	-0.34 (0.141)	-0.57 (0.113)	-0.29 (0.429)	-0.24 (0.338)	
95% CI [2]	-0.62, -0.06	-0.79, -0.35	-1.28, 0.70	-1.02, 0.54	
Difference (95% CI) in CFB [2]		-0.23 (-0.54, 0.08)		0.06 (-0.80, 0.92)	
p-value [3]		0.143		0.879	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	59	102	4	8	
Mean (StdDev)	2.2 (1.18)	2.1 (1.12)	2.5 (1.29)	2.0 (1.51)	
Median	2.0	2.0	2.5	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C3D1 CFB					
n	57	101	4	8	
LS Mean (StdErr) [2]	-0.42 (0.150)	-0.62 (0.118)	-1.71 (0.623)	-1.26 (0.491)	
95% CI [2]	-0.72, -0.13	-0.86, -0.39	-3.14, -0.27	-2.40, -0.13	
Difference (95% CI) in CFB [2]		-0.20 (-0.53, 0.13)		0.44 (-0.81, 1.69)	
p-value [3]		0.231		0.439	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	52	104	4	9	
Mean (StdDev)	2.3 (1.10)	2.0 (1.18)	3.8 (0.50)	2.6 (0.88)	
Median	2.0	2.0	4.0	3.0	
Min, Max	0, 4	0, 4	3, 4	1, 4	
C4D1 CFB					
n	50	102	4	9	
LS Mean (StdErr) [2]	-0.33 (0.177)	-0.72 (0.135)	0.50 (0.773)	-0.00 (0.612)	
95% CI [2]	-0.68, 0.02	-0.99, -0.46	-1.25, 2.25	-1.39, 1.39	
Difference (95% CI) in CFB [2]		-0.40 (-0.78, -0.02)		-0.50 (-2.01, 1.01)	
p-value [3]		0.040		0.472	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	56	100	4	9	
Mean (StdDev)	2.2 (1.10)	2.0 (1.15)	3.3 (0.96)	2.6 (0.88)	
Median	2.0	2.0	3.5	3.0	
Min, Max	0, 4	0, 4	2, 4	1, 4	
C5D1 CFB					
n	55	96	4	9	
LS Mean (StdErr) [2]	-0.38 (0.180)	-0.77 (0.143)	0.57 (0.591)	0.47 (0.468)	
95% CI [2]	-0.74, -0.02	-1.05, -0.49	-0.76, 1.91	-0.58, 1.53	
Difference (95% CI) in CFB [2]		-0.39 (-0.79, 0.01)		-0.10 (-1.25, 1.05)	
p-value [3]		0.054		0.849	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	102	4	9	
Mean (StdDev)	2.3 (1.23)	1.8 (1.15)	3.3 (0.96)	2.3 (1.00)	
Median	2.0	2.0	3.5	2.0	
Min, Max	0, 4	0, 4	2, 4	1, 4	
C6D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-0.28 (0.184)	-0.90 (0.144)	0.15 (0.749)	-0.05 (0.594)	
95% CI [2]	-0.64, 0.09	-1.19, -0.62	-1.54, 1.84	-1.39, 1.29	
Difference (95% CI) in CFB [2]		-0.63 (-1.03, -0.22)		-0.20 (-1.66, 1.26)	
p-value [3]		0.003		0.764	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	54	102	4	9	
Mean (StdDev)	2.2 (1.23)	1.8 (1.17)	3.3 (0.96)	2.3 (1.00)	
Median	2.0	2.0	3.5	2.0	
Min, Max	0, 4	0, 4	2, 4	1, 4	
C7D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-0.22 (0.180)	-0.81 (0.139)	-0.42 (0.591)	-0.53 (0.468)	
95% CI [2]	-0.57, 0.14	-1.08, -0.53	-1.76, 0.91	-1.58, 0.53	
Difference (95% CI) in CFB [2]		-0.59 (-0.98, -0.20)		-0.10 (-1.25, 1.05)	
Hedges'G (95% CI) in CFB		-0.43 (-0.78, -0.10)		-0.07 (-1.41, 1.24)	
p-value [3]		0.003		0.849	
					0.648

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	61	110	4	9	
Mean (StdDev)	2.2 (1.37)	2.0 (1.32)	2.5 (1.00)	2.7 (1.12)	
Median	2.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	1, 3	1, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	61	111	4	8	
Mean (StdDev)	1.9 (1.31)	1.6 (1.29)	2.3 (0.96)	2.6 (1.41)	
Median	2.0	2.0	2.5	2.5	
Min, Max	0, 4	0, 4	1, 3	0, 4	
C2D1 CFB					
n	59	108	4	8	
LS Mean (StdErr) [2]	-0.19 (0.139)	-0.32 (0.111)	-2.01 (0.548)	-1.16 (0.432)	
95% CI [2]	-0.47, 0.08	-0.54, -0.11	-3.28, -0.75	-2.16, -0.17	
Difference (95% CI) in CFB [2]		-0.13 (-0.44, 0.17)		0.85 (-0.25, 1.95)	
p-value [3]		0.396		0.111	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	58	102	4	8	
Mean (StdDev)	1.7 (1.29)	1.4 (1.22)	2.0 (0.82)	2.1 (1.13)	
Median	2.0	1.5	2.0	2.0	
Min, Max	0, 4	0, 4	1, 3	1, 4	
C3D1 CFB					
n	56	101	4	8	
LS Mean (StdErr) [2]	-0.41 (0.155)	-0.47 (0.121)	-1.53 (0.672)	-1.32 (0.530)	
95% CI [2]	-0.71, -0.10	-0.71, -0.24	-3.08, 0.02	-2.55, -0.10	
Difference (95% CI) in CFB [2]		-0.07 (-0.41, 0.27)		0.21 (-1.14, 1.55)	
p-value [3]		0.703		0.734	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	52	104	4	9	
Mean (StdDev)	1.8 (1.39)	1.4 (1.25)	2.0 (0.82)	3.0 (1.32)	
Median	2.0	1.0	2.0	3.0	
Min, Max	0, 4	0, 4	1, 3	0, 4	
C4D1 CFB					
n	50	102	4	9	
LS Mean (StdErr) [2]	-0.45 (0.175)	-0.61 (0.134)	-0.68 (1.061)	0.23 (0.841)	
95% CI [2]	-0.79, -0.10	-0.87, -0.34	-3.08, 1.73	-1.68, 2.13	
Difference (95% CI) in CFB [2]		-0.16 (-0.54, 0.21)		0.90 (-1.17, 2.97)	
p-value [3]		0.399		0.351	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	56	100	4	9	
Mean (StdDev)	1.7 (1.35)	1.3 (1.24)	2.3 (1.26)	2.1 (1.27)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C5D1 CFB					
n	55	96	4	9	
LS Mean (StdErr) [2]	-0.49 (0.181)	-0.72 (0.143)	-0.15 (0.749)	-0.95 (0.594)	
95% CI [2]	-0.85, -0.13	-1.00, -0.43	-1.84, 1.54	-2.29, 0.39	
Difference (95% CI) in CFB [2]		-0.23 (-0.62, 0.17)		-0.80 (-2.26, 0.66)	
p-value [3]		0.264		0.247	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	102	4	9	
Mean (StdDev)	1.9 (1.41)	1.2 (1.15)	2.3 (1.50)	2.4 (1.33)	
Median	2.0	1.0	2.0	3.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C6D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-0.23 (0.183)	-0.77 (0.143)	-0.70 (1.025)	-0.60 (0.812)	
95% CI [2]	-0.59, 0.13	-1.06, -0.49	-3.02, 1.62	-2.44, 1.24	
Difference (95% CI) in CFB [2]		-0.54 (-0.95, -0.14)		0.10 (-1.90, 2.10)	
p-value [3]		0.009		0.912	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	54	102	4	9	
Mean (StdDev)	1.8 (1.37)	1.2 (1.23)	2.3 (1.50)	2.6 (1.51)	
Median	2.0	1.0	2.0	3.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C7D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-0.30 (0.167)	-0.70 (0.129)	-0.25 (1.065)	-0.25 (0.844)	
95% CI [2]	-0.63, 0.03	-0.95, -0.45	-2.66, 2.16	-2.16, 1.66	
Difference (95% CI) in CFB [2]		-0.40 (-0.76, -0.03)		0.00 (-2.08, 2.08)	
Hedges'G (95% CI) in CFB		-0.31 (-0.66, 0.02)		0.00 (-1.32, 1.32)	
p-value [3]		0.032		>0.999	
					0.370

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	61	110	4	9	
Mean (StdDev)	2.4 (1.04)	2.5 (1.08)	2.5 (0.58)	3.0 (0.87)	
Median	2.0	2.0	2.5	3.0	
Min, Max	0, 4	0, 4	2, 3	2, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	61	111	4	8	
Mean (StdDev)	1.9 (1.08)	1.8 (1.13)	2.5 (0.58)	2.4 (1.06)	
Median	2.0	2.0	2.5	2.5	
Min, Max	0, 4	0, 4	2, 3	1, 4	
C2D1 CFB					
n	59	108	4	8	
LS Mean (StdErr) [2]	-0.45 (0.155)	-0.68 (0.123)	-0.82 (0.914)	-1.56 (0.721)	
95% CI [2]	-0.76, -0.15	-0.93, -0.44	-2.93, 1.29	-3.22, 0.10	
Difference (95% CI) in CFB [2]		-0.23 (-0.57, 0.11)		-0.74 (-2.57, 1.10)	
p-value [3]		0.184		0.382	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	59	101	4	8	
Mean (StdDev)	2.0 (1.14)	1.6 (1.03)	2.0 (0.82)	2.5 (1.31)	
Median	2.0	2.0	2.0	2.5	
Min, Max	0, 4	0, 4	1, 3	0, 4	
C3D1 CFB					
n	57	100	4	8	
LS Mean (StdErr) [2]	-0.44 (0.165)	-0.84 (0.129)	-0.82 (1.259)	-1.06 (0.992)	
95% CI [2]	-0.76, -0.11	-1.09, -0.58	-3.73, 2.08	-3.35, 1.23	
Difference (95% CI) in CFB [2]		-0.40 (-0.76, -0.04)		-0.24 (-2.76, 2.29)	
p-value [3]		0.030		0.835	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	52	104	4	9	
Mean (StdDev)	1.9 (1.15)	1.6 (1.10)	2.3 (0.50)	2.3 (1.50)	
Median	2.0	2.0	2.0	3.0	
Min, Max	0, 4	0, 4	2, 3	0, 4	
C4D1 CFB					
n	50	102	4	9	
LS Mean (StdErr) [2]	-0.58 (0.174)	-0.92 (0.133)	-0.55 (1.212)	-1.15 (0.960)	
95% CI [2]	-0.93, -0.24	-1.18, -0.65	-3.29, 2.19	-3.32, 1.02	
Difference (95% CI) in CFB [2]		-0.33 (-0.70, 0.04)		-0.60 (-2.97, 1.77)	
p-value [3]		0.081		0.580	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	56	100	4	9	
Mean (StdDev)	1.8 (1.17)	1.5 (1.12)	2.3 (1.26)	2.1 (1.27)	
Median	2.0	1.5	2.0	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C5D1 CFB					
n	55	96	4	9	
LS Mean (StdErr) [2]	-0.65 (0.182)	-1.07 (0.144)	-0.40 (1.207)	-1.20 (0.957)	
95% CI [2]	-1.01, -0.29	-1.35, -0.78	-3.13, 2.33	-3.36, 0.96	
Difference (95% CI) in CFB [2]		-0.42 (-0.82, -0.02)		-0.80 (-3.16, 1.56)	
p-value [3]		0.039		0.462	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	102	4	9	
Mean (StdDev)	1.9 (1.14)	1.4 (1.12)	2.5 (1.29)	2.3 (1.22)	
Median	2.0	1.0	2.5	3.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C6D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-0.53 (0.176)	-1.13 (0.138)	-0.28 (1.213)	-1.08 (0.961)	
95% CI [2]	-0.88, -0.18	-1.41, -0.86	-3.02, 2.47	-3.25, 1.10	
Difference (95% CI) in CFB [2]		-0.60 (-0.99, -0.22)		-0.80 (-3.17, 1.57)	
p-value [3]		0.002		0.464	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	54	102	4	9	
Mean (StdDev)	1.8 (1.28)	1.4 (1.25)	2.5 (1.00)	2.2 (1.48)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	2, 4	0, 4	
C7D1 CFB					
n	53	98	4	9	
LS Mean (StdErr) [2]	-0.46 (0.204)	-1.01 (0.157)	0.28 (1.163)	-0.93 (0.922)	
95% CI [2]	-0.86, -0.05	-1.32, -0.70	-2.36, 2.91	-3.01, 1.16	
Difference (95% CI) in CFB [2]		-0.55 (-0.99, -0.11)		-1.20 (-3.47, 1.07)	
Hedges'G (95% CI) in CFB		-0.36 (-0.70, -0.03)		-0.42 (-1.85, 0.82)	
p-value [3]		0.014		0.262	
					0.765

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	60	110	4	9	
Mean (StdDev)	2.1 (1.27)	2.2 (1.19)	2.3 (1.26)	2.4 (1.13)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	1, 4	1, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	61	111	4	8	
Mean (StdDev)	1.9 (1.22)	1.8 (1.17)	2.3 (1.50)	2.0 (1.31)	
Median	2.0	2.0	2.0	2.5	
Min, Max	0, 4	0, 4	1, 4	0, 3	
C2D1 CFB					
n	58	108	4	8	
LS Mean (StdErr) [2]	-0.15 (0.149)	-0.46 (0.118)	-0.29 (1.066)	-0.24 (0.840)	
95% CI [2]	-0.44, 0.14	-0.69, -0.22	-2.75, 2.16	-2.17, 1.70	
Difference (95% CI) in CFB [2]		-0.30 (-0.63, 0.02)		0.06 (-2.08, 2.20)	
p-value [3]		0.067		0.951	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	59	102	4	8	
Mean (StdDev)	1.8 (1.22)	1.6 (1.08)	2.0 (0.82)	1.9 (1.36)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	1, 3	0, 4	
C3D1 CFB					
n	56	101	4	8	
LS Mean (StdErr) [2]	-0.17 (0.149)	-0.62 (0.117)	0.63 (0.879)	0.46 (0.693)	
95% CI [2]	-0.47, 0.12	-0.85, -0.39	-1.39, 2.66	-1.14, 2.05	
Difference (95% CI) in CFB [2]		-0.45 (-0.77, -0.12)		-0.18 (-1.94, 1.59)	
p-value [3]		0.008		0.823	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	52	104	4	9	
Mean (StdDev)	1.8 (1.27)	1.6 (1.21)	2.5 (0.58)	2.1 (1.62)	
Median	2.0	1.0	2.5	3.0	
Min, Max	0, 4	0, 4	2, 3	0, 4	
C4D1 CFB					
n	49	102	4	9	
LS Mean (StdErr) [2]	-0.26 (0.181)	-0.66 (0.138)	0.55 (0.934)	0.15 (0.740)	
95% CI [2]	-0.62, 0.10	-0.93, -0.39	-1.56, 2.66	-1.52, 1.82	
Difference (95% CI) in CFB [2]		-0.40 (-0.79, -0.01)		-0.40 (-2.22, 1.42)	
p-value [3]		0.042		0.631	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	56	100	4	9	
Mean (StdDev)	1.7 (1.14)	1.4 (1.11)	1.5 (0.58)	2.2 (1.39)	
Median	2.0	1.0	1.5	3.0	
Min, Max	0, 4	0, 4	1, 2	0, 4	
C5D1 CFB					
n	54	96	4	9	
LS Mean (StdErr) [2]	-0.24 (0.171)	-0.77 (0.135)	0.53 (0.935)	0.83 (0.741)	
95% CI [2]	-0.58, 0.09	-1.04, -0.50	-1.59, 2.64	-0.85, 2.50	
Difference (95% CI) in CFB [2]		-0.52 (-0.90, -0.15)		0.30 (-1.53, 2.13)	
p-value [3]		0.007		0.719	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	102	4	9	
Mean (StdDev)	1.8 (1.25)	1.4 (1.19)	1.8 (0.50)	2.3 (1.32)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	1, 2	0, 4	
C6D1 CFB					
n	52	98	4	9	
LS Mean (StdErr) [2]	-0.20 (0.177)	-0.89 (0.137)	0.78 (0.903)	1.08 (0.715)	
95% CI [2]	-0.55, 0.15	-1.16, -0.62	-1.27, 2.82	-0.54, 2.69	
Difference (95% CI) in CFB [2]		-0.69 (-1.08, -0.30)		0.30 (-1.46, 2.06)	
p-value [3]		<0.001		0.709	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	54	102	4	9	
Mean (StdDev)	1.7 (1.22)	1.5 (1.23)	1.8 (0.50)	2.1 (1.54)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	1, 2	0, 4	
C7D1 CFB					
n	52	98	4	9	
LS Mean (StdErr) [2]	-0.09 (0.188)	-0.62 (0.144)	0.93 (0.942)	1.03 (0.746)	
95% CI [2]	-0.46, 0.28	-0.91, -0.34	-1.21, 3.06	-0.66, 2.71	
Difference (95% CI) in CFB [2]		-0.53 (-0.94, -0.12)		0.10 (-1.74, 1.94)	
Hedges'G (95% CI) in CFB		-0.38 (-0.72, -0.04)		0.04 (-1.27, 1.38)	
p-value [3]		0.011		0.905	
					0.320

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-ecog-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	62	109	
Mean (StdDev)	3.7 (0.58)	3.3 (0.95)	2.7 (1.13)	2.3 (1.07)	
Median	4.0	4.0	3.0	2.0	
Min, Max	3, 4	2, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-thpy-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	62	109	
Mean (StdDev)	3.3 (0.58)	2.3 (0.95)	2.3 (1.02)	1.6 (0.88)	
Median	3.0	2.5	2.0	2.0	
Min, Max	3, 4	0, 3	0, 4	0, 4	
C2D1 CFB					
n	3	10	60	106	
LS Mean (StdErr) [2]	-0.32 (0.837)	-0.91 (0.741)	-0.38 (0.153)	-0.55 (0.123)	
95% CI [2]	-2.22, 1.57	-2.59, 0.76	-0.68, -0.08	-0.79, -0.31	
Difference (95% CI) in CFB [2]		-0.59 (-2.76, 1.57)		-0.17 (-0.51, 0.16)	
p-value [3]		0.552		0.306	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	10	60	100	
Mean (StdDev)	2.3 (0.58)	1.9 (0.99)	2.1 (1.15)	1.5 (0.93)	
Median	2.0	2.0	2.0	1.0	
Min, Max	2, 3	0, 3	0, 4	0, 4	
C3D1 CFB					
n	3	10	58	99	
LS Mean (StdErr) [2]	-1.32 (0.969)	-1.34 (0.857)	-0.55 (0.165)	-0.68 (0.131)	
95% CI [2]	-3.51, 0.87	-3.28, 0.60	-0.88, -0.23	-0.94, -0.42	
Difference (95% CI) in CFB [2]		-0.02 (-2.53, 2.49)		-0.12 (-0.49, 0.24)	
p-value [3]		0.986		0.497	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	2	9	54	104	
Mean (StdDev)	3.5 (0.71)	1.4 (0.88)	2.2 (1.07)	1.4 (1.04)	
Median	3.5	1.0	2.0	1.0	
Min, Max	3, 4	0, 3	0, 4	0, 4	
C4D1 CFB					
n	2	9	52	102	
LS Mean (StdErr) [2]	-0.30 (1.143)	-1.57 (0.763)	-0.48 (0.179)	-0.80 (0.140)	
95% CI [2]	-3.01, 2.40	-3.37, 0.24	-0.83, -0.12	-1.08, -0.53	
Difference (95% CI) in CFB [2]		-1.26 (-4.11, 1.58)		-0.33 (-0.71, 0.06)	
p-value [3]		0.329		0.095	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	8	57	100	
Mean (StdDev)	3.0 (1.00)	1.5 (1.31)	2.2 (1.20)	1.4 (0.95)	
Median	3.0	1.0	2.0	1.0	
Min, Max	2, 4	0, 3	0, 4	0, 4	
C5D1 CFB					
n	3	8	56	96	
LS Mean (StdErr) [2]	-0.48 (1.124)	-1.23 (0.993)	-0.35 (0.176)	-0.80 (0.140)	
95% CI [2]	-3.14, 2.18	-3.58, 1.12	-0.69, 0.00	-1.08, -0.52	
Difference (95% CI) in CFB [2]		-0.75 (-3.81, 2.31)		-0.46 (-0.84, -0.07)	
p-value [3]		0.580		0.020	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	55	102	
Mean (StdDev)	3.0 (1.00)	1.3 (1.00)	2.1 (1.20)	1.5 (1.04)	
Median	3.0	1.0	2.0	1.0	
Min, Max	2, 4	0, 3	0, 4	0, 4	
C6D1 CFB					
n	3	9	54	98	
LS Mean (StdErr) [2]	-0.28 (1.018)	-1.09 (0.900)	-0.56 (0.172)	-0.77 (0.135)	
95% CI [2]	-2.62, 2.07	-3.16, 0.99	-0.90, -0.22	-1.04, -0.50	
Difference (95% CI) in CFB [2]		-0.81 (-3.50, 1.88)		-0.21 (-0.59, 0.17)	
p-value [3]		0.506		0.272	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Itching	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	8	55	103	
Mean (StdDev)	3.0 (1.00)	1.1 (0.64)	2.3 (1.15)	1.3 (0.97)	
Median	3.0	1.0	2.0	1.0	
Min, Max	2, 4	0, 2	0, 4	0, 4	
C7D1 CFB					
n	3	8	54	99	
LS Mean (StdErr) [2]	-0.25 (0.735)	-1.25 (0.649)	-0.36 (0.170)	-0.79 (0.131)	
95% CI [2]	-1.99, 1.49	-2.79, 0.29	-0.70, -0.03	-1.05, -0.53	
Difference (95% CI) in CFB [2]		-1.00 (-3.00, 1.00)		-0.43 (-0.79, -0.06)	
Hedges'G (95% CI) in CFB		-0.53 (-2.24, 0.88)		-0.33 (-0.67, 0.00)	
p-value [3]		0.275		0.022	
					0.247

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	62	109	
Mean (StdDev)	3.0 (1.73)	2.6 (1.35)	2.5 (1.14)	2.1 (1.11)	
Median	4.0	3.0	3.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	62	109	
Mean (StdDev)	3.7 (0.58)	1.2 (0.79)	2.1 (1.10)	1.5 (1.01)	
Median	4.0	1.0	2.0	1.0	
Min, Max	3, 4	0, 2	0, 4	0, 4	
C2D1 CFB					
n	3	10	60	106	
LS Mean (StdErr) [2]	0.68 (0.969)	-1.34 (0.857)	-0.23 (0.161)	-0.51 (0.129)	
95% CI [2]	-1.51, 2.87	-3.28, 0.60	-0.55, 0.09	-0.76, -0.26	
Difference (95% CI) in CFB [2]		-2.02 (-4.53, 0.49)		-0.28 (-0.63, 0.07)	
p-value [3]		0.101		0.116	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	10	60	100	
Mean (StdDev)	2.0 (1.00)	1.5 (0.85)	2.2 (1.25)	1.4 (1.02)	
Median	2.0	1.5	2.0	1.0	
Min, Max	1, 3	0, 3	0, 4	0, 4	
C3D1 CFB					
n	3	10	58	99	
LS Mean (StdErr) [2]	-1.18 (0.851)	-1.44 (0.753)	-0.28 (0.178)	-0.56 (0.141)	
95% CI [2]	-3.10, 0.75	-3.15, 0.26	-0.63, 0.07	-0.84, -0.28	
Difference (95% CI) in CFB [2]		-0.27 (-2.47, 1.94)		-0.28 (-0.67, 0.10)	
p-value [3]		0.791		0.150	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	2	9	54	104	
Mean (StdDev)	3.5 (0.71)	1.3 (1.12)	2.1 (1.05)	1.3 (1.04)	
Median	3.5	1.0	2.0	1.0	
Min, Max	3, 4	0, 3	0, 4	0, 4	
C4D1 CFB					
n	2	9	52	102	
LS Mean (StdErr) [2]	-1.09 (0.968)	-1.30 (0.646)	-0.19 (0.179)	-0.66 (0.140)	
95% CI [2]	-3.38, 1.20	-2.83, 0.23	-0.54, 0.17	-0.94, -0.38	
Difference (95% CI) in CFB [2]		-0.21 (-2.62, 2.20)		-0.47 (-0.86, -0.09)	
p-value [3]		0.842		0.017	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	8	57	100	
Mean (StdDev)	3.0 (1.00)	1.1 (0.83)	2.1 (1.27)	1.4 (0.99)	
Median	3.0	1.0	2.0	1.0	
Min, Max	2, 4	0, 3	0, 4	0, 4	
C5D1 CFB					
n	3	8	56	96	
LS Mean (StdErr) [2]	0.26 (0.868)	-0.90 (0.767)	-0.24 (0.178)	-0.56 (0.142)	
95% CI [2]	-1.79, 2.32	-2.72, 0.91	-0.60, 0.11	-0.84, -0.28	
Difference (95% CI) in CFB [2]		-1.17 (-3.53, 1.19)		-0.32 (-0.71, 0.07)	
p-value [3]		0.281		0.107	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	55	102	
Mean (StdDev)	3.3 (0.58)	1.7 (1.00)	2.1 (1.17)	1.5 (1.10)	
Median	3.0	1.0	2.0	1.0	
Min, Max	3, 4	1, 3	0, 4	0, 4	
C6D1 CFB					
n	3	9	54	98	
LS Mean (StdErr) [2]	0.69 (1.071)	-0.35 (0.947)	-0.22 (0.179)	-0.57 (0.140)	
95% CI [2]	-1.78, 3.16	-2.54, 1.83	-0.58, 0.13	-0.85, -0.30	
Difference (95% CI) in CFB [2]		-1.05 (-3.88, 1.78)		-0.35 (-0.74, 0.04)	
p-value [3]		0.418		0.078	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	8	55	103	
Mean (StdDev)	2.7 (1.53)	0.8 (0.46)	2.1 (1.18)	1.4 (1.11)	
Median	3.0	1.0	2.0	1.0	
Min, Max	1, 4	0, 1	0, 4	0, 4	
C7D1 CFB					
n	3	8	54	99	
LS Mean (StdErr) [2]	-0.06 (0.526)	-1.39 (0.464)	-0.11 (0.189)	-0.43 (0.145)	
95% CI [2]	-1.30, 1.19	-2.49, -0.29	-0.49, 0.26	-0.72, -0.14	
Difference (95% CI) in CFB [2]		-1.33 (-2.76, 0.10)		-0.31 (-0.72, 0.09)	
Hedges'G (95% CI) in CFB		-0.99 (-2.89, 0.36)		-0.22 (-0.56, 0.11)	
p-value [3]		0.063		0.126	
					0.143

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	62	109	
Mean (StdDev)	1.3 (0.58)	2.7 (1.34)	2.3 (1.14)	2.4 (1.06)	
Median	1.0	3.0	2.5	2.0	
Min, Max	1, 2	1, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	62	109	
Mean (StdDev)	1.3 (0.58)	1.7 (1.34)	2.1 (1.10)	1.9 (1.05)	
Median	1.0	1.5	2.0	2.0	
Min, Max	1, 2	0, 4	0, 4	0, 4	
C2D1 CFB					
n	3	10	60	106	
LS Mean (StdErr) [2]	-0.11 (0.751)	-1.21 (0.664)	-0.16 (0.146)	-0.36 (0.117)	
95% CI [2]	-1.81, 1.59	-2.71, 0.29	-0.44, 0.13	-0.59, -0.12	
Difference (95% CI) in CFB [2]		-1.10 (-3.04, 0.84)		-0.20 (-0.52, 0.12)	
p-value [3]		0.231		0.218	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	10	60	100	
Mean (StdDev)	2.0 (1.00)	1.6 (1.26)	2.0 (1.04)	1.8 (1.09)	
Median	2.0	1.5	2.0	2.0	
Min, Max	1, 3	0, 4	0, 4	0, 4	
C3D1 CFB					
n	3	10	58	99	
LS Mean (StdErr) [2]	0.71 (0.811)	-0.94 (0.718)	-0.20 (0.164)	-0.40 (0.129)	
95% CI [2]	-1.12, 2.55	-2.56, 0.68	-0.52, 0.12	-0.66, -0.15	
Difference (95% CI) in CFB [2]		-1.65 (-3.75, 0.44)		-0.20 (-0.56, 0.15)	
p-value [3]		0.108		0.262	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	2	9	54	104	
Mean (StdDev)	1.5 (0.71)	1.3 (0.87)	2.1 (1.15)	1.8 (1.04)	
Median	1.5	1.0	2.0	2.0	
Min, Max	1, 2	0, 3	0, 4	0, 4	
C4D1 CFB					
n	2	9	52	102	
LS Mean (StdErr) [2]	0.12 (0.779)	-1.04 (0.520)	-0.12 (0.175)	-0.44 (0.136)	
95% CI [2]	-1.72, 1.96	-2.27, 0.19	-0.46, 0.23	-0.71, -0.17	
Difference (95% CI) in CFB [2]		-1.16 (-3.10, 0.78)		-0.32 (-0.70, 0.05)	
p-value [3]		0.201		0.090	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	8	57	100	
Mean (StdDev)	1.3 (0.58)	1.3 (1.04)	2.1 (1.25)	1.8 (1.08)	
Median	1.0	1.0	2.0	2.0	
Min, Max	1, 2	0, 3	0, 4	0, 4	
C5D1 CFB					
n	3	8	56	96	
LS Mean (StdErr) [2]	0.08 (0.799)	-1.34 (0.706)	-0.19 (0.182)	-0.46 (0.145)	
95% CI [2]	-1.81, 1.97	-3.01, 0.33	-0.55, 0.17	-0.75, -0.17	
Difference (95% CI) in CFB [2]		-1.42 (-3.59, 0.76)		-0.27 (-0.67, 0.13)	
p-value [3]		0.167		0.183	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	55	102	
Mean (StdDev)	1.7 (1.15)	1.4 (1.33)	1.9 (1.21)	1.7 (1.12)	
Median	1.0	1.0	2.0	2.0	
Min, Max	1, 3	0, 3	0, 4	0, 4	
C6D1 CFB					
n	3	9	54	98	
LS Mean (StdErr) [2]	0.41 (0.887)	-1.29 (0.784)	-0.26 (0.177)	-0.50 (0.139)	
95% CI [2]	-1.63, 2.46	-3.10, 0.51	-0.61, 0.09	-0.78, -0.23	
Difference (95% CI) in CFB [2]		-1.71 (-4.05, 0.64)		-0.24 (-0.63, 0.14)	
p-value [3]		0.132		0.214	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	8	55	103	
Mean (StdDev)	1.3 (0.58)	1.1 (1.13)	1.9 (1.14)	1.7 (1.10)	
Median	1.0	1.0	2.0	2.0	
Min, Max	1, 2	0, 3	0, 4	0, 4	
C7D1 CFB					
n	3	8	54	99	
LS Mean (StdErr) [2]	0.01 (0.636)	-1.58 (0.562)	-0.32 (0.192)	-0.53 (0.148)	
95% CI [2]	-1.50, 1.51	-2.90, -0.25	-0.70, 0.06	-0.82, -0.24	
Difference (95% CI) in CFB [2]		-1.58 (-3.31, 0.15)		-0.21 (-0.62, 0.20)	
Hedges'G (95% CI) in CFB		-0.97 (-2.87, 0.38)		-0.14 (-0.48, 0.19)	
p-value [3]		0.067		0.312	
					0.113

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	62	109	
Mean (StdDev)	1.7 (1.53)	2.2 (1.32)	2.1 (1.19)	2.1 (1.21)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	62	108	
Mean (StdDev)	1.7 (0.58)	1.7 (1.34)	1.7 (1.19)	1.5 (1.11)	
Median	2.0	1.5	2.0	1.0	
Min, Max	1, 2	0, 4	0, 4	0, 4	
C2D1 CFB					
n	3	10	60	105	
LS Mean (StdErr) [2]	-0.07 (1.124)	-0.66 (0.994)	-0.28 (0.163)	-0.51 (0.132)	
95% CI [2]	-2.61, 2.47	-2.91, 1.59	-0.60, 0.04	-0.77, -0.25	
Difference (95% CI) in CFB [2]		-0.59 (-3.50, 2.31)		-0.23 (-0.58, 0.13)	
p-value [3]		0.656		0.208	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	10	60	100	
Mean (StdDev)	1.3 (0.58)	1.0 (0.82)	1.8 (1.31)	1.6 (1.16)	
Median	1.0	1.0	2.0	1.0	
Min, Max	1, 2	0, 2	0, 4	0, 4	
C3D1 CFB					
n	3	10	58	99	
LS Mean (StdErr) [2]	-0.54 (0.939)	-1.62 (0.830)	-0.18 (0.186)	-0.44 (0.147)	
95% CI [2]	-2.66, 1.59	-3.50, 0.26	-0.54, 0.19	-0.73, -0.15	
Difference (95% CI) in CFB [2]		-1.08 (-3.51, 1.35)		-0.27 (-0.67, 0.14)	
p-value [3]		0.340		0.196	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-thpy-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	2	9	54	104	
Mean (StdDev)	1.5 (0.71)	1.3 (0.87)	1.8 (1.23)	1.5 (1.21)	
Median	1.5	1.0	2.0	1.0	
Min, Max	1, 2	0, 3	0, 4	0, 4	
C4D1 CFB					
n	2	9	52	102	
LS Mean (StdErr) [2]	-1.53 (0.990)	-1.16 (0.661)	-0.28 (0.183)	-0.48 (0.143)	
95% CI [2]	-3.87, 0.81	-2.72, 0.40	-0.65, 0.08	-0.77, -0.20	
Difference (95% CI) in CFB [2]		0.37 (-2.10, 2.83)		-0.20 (-0.59, 0.19)	
p-value [3]		0.734		0.315	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	8	57	100	
Mean (StdDev)	1.0 (1.00)	1.1 (0.99)	1.9 (1.09)	1.5 (1.18)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 2	0, 3	0, 4	0, 4	
C5D1 CFB					
n	3	8	56	96	
LS Mean (StdErr) [2]	-0.46 (0.717)	-0.96 (0.633)	-0.12 (0.188)	-0.60 (0.150)	
95% CI [2]	-2.15, 1.24	-2.45, 0.54	-0.49, 0.25	-0.90, -0.31	
Difference (95% CI) in CFB [2]		-0.50 (-2.45, 1.45)		-0.49 (-0.90, -0.07)	
p-value [3]		0.563		0.021	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	55	102	
Mean (StdDev)	1.3 (0.58)	1.0 (0.87)	1.8 (1.21)	1.4 (1.16)	
Median	1.0	1.0	2.0	1.0	
Min, Max	1, 2	0, 3	0, 4	0, 4	
C6D1 CFB					
n	3	9	54	98	
LS Mean (StdErr) [2]	-0.19 (0.823)	-1.15 (0.727)	-0.16 (0.187)	-0.55 (0.146)	
95% CI [2]	-2.09, 1.70	-2.82, 0.53	-0.53, 0.21	-0.83, -0.26	
Difference (95% CI) in CFB [2]		-0.95 (-3.13, 1.22)		-0.38 (-0.79, 0.02)	
p-value [3]		0.341		0.064	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	8	55	103	
Mean (StdDev)	2.0 (1.00)	0.8 (0.46)	1.7 (1.10)	1.5 (1.27)	
Median	2.0	1.0	2.0	1.0	
Min, Max	1, 3	0, 1	0, 4	0, 4	
C7D1 CFB					
n	3	8	54	99	
LS Mean (StdErr) [2]	0.60 (0.997)	-1.15 (0.880)	-0.17 (0.186)	-0.44 (0.143)	
95% CI [2]	-1.75, 2.96	-3.23, 0.94	-0.53, 0.20	-0.72, -0.16	
Difference (95% CI) in CFB [2]		-1.75 (-4.46, 0.96)		-0.27 (-0.67, 0.13)	
Hedges'G (95% CI) in CFB		-0.68 (-2.46, 0.70)		-0.19 (-0.53, 0.14)	
p-value [3]		0.170		0.180	
					0.068

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	62	109	
Mean (StdDev)	2.3 (0.58)	3.3 (0.82)	3.2 (0.91)	3.2 (0.87)	
Median	2.0	3.5	3.0	3.0	
Min, Max	2, 3	2, 4	1, 4	1, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	62	109	
Mean (StdDev)	2.0 (0.00)	2.4 (1.65)	2.8 (0.96)	2.8 (1.02)	
Median	2.0	2.5	3.0	3.0	
Min, Max	2, 2	0, 4	1, 4	0, 4	
C2D1 CFB					
n	3	10	60	106	
LS Mean (StdErr) [2]	-0.82 (0.597)	-1.84 (0.528)	-0.31 (0.135)	-0.46 (0.108)	
95% CI [2]	-2.17, 0.53	-3.04, -0.65	-0.57, -0.04	-0.67, -0.25	
Difference (95% CI) in CFB [2]		-1.02 (-2.56, 0.52)		-0.15 (-0.45, 0.14)	
p-value [3]		0.169		0.304	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	10	60	100	
Mean (StdDev)	3.0 (1.00)	2.4 (1.26)	2.7 (1.11)	2.5 (1.08)	
Median	3.0	2.0	3.0	3.0	
Min, Max	2, 4	1, 4	0, 4	0, 4	
C3D1 CFB					
n	3	10	58	99	
LS Mean (StdErr) [2]	0.36 (0.541)	-1.54 (0.478)	-0.47 (0.162)	-0.67 (0.128)	
95% CI [2]	-0.87, 1.58	-2.62, -0.46	-0.79, -0.15	-0.92, -0.42	
Difference (95% CI) in CFB [2]		-1.90 (-3.30, -0.50)		-0.20 (-0.56, 0.15)	
p-value [3]		0.013		0.262	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	2	9	54	104	
Mean (StdDev)	2.0 (0.00)	2.4 (1.42)	2.8 (1.14)	2.5 (1.09)	
Median	2.0	2.0	3.0	3.0	
Min, Max	2, 2	0, 4	1, 4	0, 4	
C4D1 CFB					
n	2	9	52	102	
LS Mean (StdErr) [2]	-0.76 (0.954)	-1.08 (0.636)	-0.41 (0.174)	-0.66 (0.136)	
95% CI [2]	-3.02, 1.49	-2.58, 0.43	-0.75, -0.07	-0.93, -0.39	
Difference (95% CI) in CFB [2]		-0.32 (-2.69, 2.06)		-0.25 (-0.62, 0.12)	
p-value [3]		0.762		0.189	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	8	57	100	
Mean (StdDev)	2.3 (0.58)	2.3 (1.49)	2.7 (1.23)	2.4 (1.13)	
Median	2.0	2.5	3.0	2.5	
Min, Max	2, 3	0, 4	0, 4	0, 4	
C5D1 CFB					
n	3	8	56	96	
LS Mean (StdErr) [2]	-0.12 (0.545)	-1.20 (0.481)	-0.40 (0.170)	-0.76 (0.136)	
95% CI [2]	-1.41, 1.17	-2.34, -0.06	-0.74, -0.07	-1.03, -0.49	
Difference (95% CI) in CFB [2]		-1.08 (-2.56, 0.40)		-0.36 (-0.73, 0.02)	
p-value [3]		0.127		0.060	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	55	102	
Mean (StdDev)	2.3 (0.58)	1.9 (1.45)	2.7 (1.13)	2.4 (1.16)	
Median	2.0	2.0	3.0	2.0	
Min, Max	2, 3	0, 4	0, 4	0, 4	
C6D1 CFB					
n	3	9	54	98	
LS Mean (StdErr) [2]	-0.18 (0.777)	-1.59 (0.687)	-0.55 (0.176)	-0.82 (0.138)	
95% CI [2]	-1.97, 1.61	-3.17, -0.00	-0.90, -0.20	-1.09, -0.55	
Difference (95% CI) in CFB [2]		-1.41 (-3.46, 0.64)		-0.27 (-0.65, 0.12)	
p-value [3]		0.151		0.169	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	8	55	103	
Mean (StdDev)	2.3 (0.58)	2.1 (1.36)	2.6 (1.11)	2.4 (1.11)	
Median	2.0	2.0	3.0	2.0	
Min, Max	2, 3	0, 4	0, 4	0, 4	
C7D1 CFB					
n	3	8	54	99	
LS Mean (StdErr) [2]	-0.20 (0.729)	-1.28 (0.643)	-0.49 (0.172)	-0.74 (0.133)	
95% CI [2]	-1.92, 1.52	-2.81, 0.24	-0.83, -0.15	-1.00, -0.47	
Difference (95% CI) in CFB [2]		-1.08 (-3.06, 0.90)		-0.25 (-0.61, 0.12)	
Hedges'G (95% CI) in CFB		-0.58 (-2.31, 0.82)		-0.19 (-0.52, 0.15)	
p-value [3]		0.237		0.192	
					0.358

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	62	109	
Mean (StdDev)	1.7 (0.58)	2.2 (1.14)	2.2 (1.15)	2.2 (1.04)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 2	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	62	109	
Mean (StdDev)	1.0 (0.00)	2.0 (1.33)	2.0 (1.10)	1.9 (0.96)	
Median	1.0	2.0	2.0	2.0	
Min, Max	1, 1	0, 4	0, 4	0, 4	
C2D1 CFB					
n	3	10	60	106	
LS Mean (StdErr) [2]	-0.96 (0.690)	-0.74 (0.611)	-0.07 (0.130)	-0.27 (0.104)	
95% CI [2]	-2.53, 0.60	-2.12, 0.64	-0.33, 0.18	-0.47, -0.06	
Difference (95% CI) in CFB [2]		0.22 (-1.56, 2.01)		-0.19 (-0.48, 0.09)	
p-value [3]		0.782		0.179	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	10	60	100	
Mean (StdDev)	0.7 (1.15)	2.1 (0.99)	1.9 (1.09)	1.6 (0.96)	
Median	0.0	2.0	2.0	2.0	
Min, Max	0, 2	1, 4	0, 4	0, 4	
C3D1 CFB					
n	3	10	58	99	
LS Mean (StdErr) [2]	-1.39 (0.581)	-0.86 (0.514)	-0.15 (0.155)	-0.52 (0.122)	
95% CI [2]	-2.71, -0.08	-2.02, 0.30	-0.46, 0.15	-0.76, -0.28	
Difference (95% CI) in CFB [2]		0.53 (-0.97, 2.03)		-0.37 (-0.71, -0.03)	
p-value [3]		0.445		0.032	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-thpy-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	2	9	54	104	
Mean (StdDev)	1.5 (0.71)	2.3 (1.32)	2.0 (1.21)	1.7 (1.13)	
Median	1.5	2.0	2.0	2.0	
Min, Max	1, 2	1, 4	0, 4	0, 4	
C4D1 CFB					
n	2	9	52	102	
LS Mean (StdErr) [2]	-0.99 (0.760)	-0.67 (0.507)	-0.13 (0.170)	-0.33 (0.132)	
95% CI [2]	-2.78, 0.81	-1.87, 0.53	-0.46, 0.21	-0.59, -0.07	
Difference (95% CI) in CFB [2]		0.32 (-1.58, 2.21)		-0.20 (-0.57, 0.16)	
p-value [3]		0.705		0.269	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	8	57	100	
Mean (StdDev)	1.3 (1.53)	1.9 (0.83)	2.0 (1.23)	1.7 (1.14)	
Median	1.0	2.0	2.0	2.0	
Min, Max	0, 3	1, 3	0, 4	0, 4	
C5D1 CFB					
n	3	8	56	96	
LS Mean (StdErr) [2]	-0.56 (0.962)	-0.89 (0.849)	-0.19 (0.156)	-0.39 (0.124)	
95% CI [2]	-2.83, 1.72	-2.90, 1.12	-0.50, 0.12	-0.64, -0.15	
Difference (95% CI) in CFB [2]		-0.33 (-2.95, 2.28)		-0.20 (-0.54, 0.14)	
p-value [3]		0.772		0.241	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	55	102	
Mean (StdDev)	0.7 (0.58)	1.8 (1.20)	2.0 (1.07)	1.6 (1.15)	
Median	1.0	2.0	2.0	2.0	
Min, Max	0, 1	0, 4	0, 4	0, 4	
C6D1 CFB					
n	3	9	54	98	
LS Mean (StdErr) [2]	-1.16 (0.596)	-0.88 (0.527)	-0.16 (0.157)	-0.45 (0.123)	
95% CI [2]	-2.54, 0.21	-2.10, 0.33	-0.47, 0.15	-0.69, -0.21	
Difference (95% CI) in CFB [2]		0.28 (-1.29, 1.86)		-0.28 (-0.63, 0.06)	
p-value [3]		0.690		0.102	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	8	55	103	
Mean (StdDev)	1.0 (1.00)	1.5 (0.93)	1.8 (1.09)	1.6 (1.11)	
Median	1.0	1.5	2.0	1.0	
Min, Max	0, 2	0, 3	0, 4	0, 4	
C7D1 CFB					
n	3	8	54	99	
LS Mean (StdErr) [2]	-0.70 (0.650)	-0.78 (0.574)	-0.28 (0.157)	-0.46 (0.121)	
95% CI [2]	-2.24, 0.84	-2.14, 0.57	-0.59, 0.03	-0.69, -0.22	
Difference (95% CI) in CFB [2]		-0.08 (-1.85, 1.68)		-0.18 (-0.51, 0.16)	
Hedges'G (95% CI) in CFB		-0.05 (-1.60, 1.47)		-0.15 (-0.49, 0.18)	
p-value [3]		0.914		0.297	
					0.870

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	62	109	
Mean (StdDev)	1.7 (1.15)	3.6 (0.52)	2.8 (1.15)	2.7 (1.15)	
Median	1.0	4.0	3.0	3.0	
Min, Max	1, 3	3, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	62	108	
Mean (StdDev)	1.3 (1.15)	2.9 (1.37)	2.4 (1.07)	2.1 (1.06)	
Median	2.0	3.5	2.0	2.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	
C2D1 CFB					
n	3	10	60	105	
LS Mean (StdErr) [2]	-0.54 (0.817)	-1.05 (0.722)	-0.27 (0.130)	-0.40 (0.105)	
95% CI [2]	-2.38, 1.31	-2.68, 0.59	-0.53, -0.02	-0.61, -0.19	
Difference (95% CI) in CFB [2]		-0.51 (-2.62, 1.60)		-0.13 (-0.41, 0.15)	
p-value [3]		0.598		0.368	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	10	60	100	
Mean (StdDev)	1.3 (1.15)	2.6 (1.17)	2.3 (1.13)	2.1 (1.22)	
Median	2.0	2.5	2.0	2.0	
Min, Max	0, 2	1, 4	0, 4	0, 4	
C3D1 CFB					
n	3	10	58	99	
LS Mean (StdErr) [2]	-0.43 (0.683)	-1.12 (0.604)	-0.47 (0.166)	-0.54 (0.131)	
95% CI [2]	-1.97, 1.12	-2.49, 0.24	-0.80, -0.14	-0.80, -0.29	
Difference (95% CI) in CFB [2]		-0.69 (-2.46, 1.07)		-0.08 (-0.44, 0.29)	
p-value [3]		0.397		0.677	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	2	9	54	104	
Mean (StdDev)	2.5 (0.71)	2.9 (1.05)	2.4 (1.18)	2.1 (1.22)	
Median	2.5	3.0	3.0	2.0	
Min, Max	2, 3	1, 4	0, 4	0, 4	
C4D1 CFB					
n	2	9	52	102	
LS Mean (StdErr) [2]	-0.32 (0.842)	-0.89 (0.562)	-0.26 (0.188)	-0.52 (0.146)	
95% CI [2]	-2.31, 1.68	-2.22, 0.43	-0.64, 0.11	-0.81, -0.23	
Difference (95% CI) in CFB [2]		-0.58 (-2.68, 1.52)		-0.25 (-0.65, 0.15)	
p-value [3]		0.535		0.216	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	8	57	100	
Mean (StdDev)	1.7 (0.58)	2.9 (0.99)	2.5 (1.14)	2.2 (1.20)	
Median	2.0	3.0	3.0	2.0	
Min, Max	1, 2	1, 4	0, 4	0, 4	
C5D1 CFB					
n	3	8	56	96	
LS Mean (StdErr) [2]	-0.03 (0.727)	-0.69 (0.642)	-0.24 (0.162)	-0.50 (0.129)	
95% CI [2]	-1.75, 1.69	-2.21, 0.82	-0.56, 0.08	-0.76, -0.25	
Difference (95% CI) in CFB [2]		-0.67 (-2.64, 1.31)		-0.26 (-0.62, 0.09)	
p-value [3]		0.451		0.144	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	55	102	
Mean (StdDev)	1.3 (1.15)	2.4 (1.13)	2.5 (1.20)	2.1 (1.21)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 2	1, 4	0, 4	0, 4	
C6D1 CFB					
n	3	9	54	98	
LS Mean (StdErr) [2]	-0.39 (0.699)	-1.15 (0.618)	-0.26 (0.176)	-0.60 (0.138)	
95% CI [2]	-2.01, 1.22	-2.57, 0.28	-0.60, 0.09	-0.88, -0.33	
Difference (95% CI) in CFB [2]		-0.75 (-2.60, 1.09)		-0.35 (-0.73, 0.03)	
p-value [3]		0.374		0.074	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	8	55	103	
Mean (StdDev)	1.7 (1.53)	2.3 (1.16)	2.3 (1.18)	2.1 (1.18)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 3	1, 4	0, 4	0, 4	
C7D1 CFB					
n	3	8	54	99	
LS Mean (StdErr) [2]	-0.07 (0.889)	-1.24 (0.785)	-0.33 (0.165)	-0.41 (0.127)	
95% CI [2]	-2.17, 2.03	-3.09, 0.62	-0.66, -0.01	-0.66, -0.16	
Difference (95% CI) in CFB [2]		-1.17 (-3.58, 1.25)		-0.08 (-0.43, 0.28)	
Hedges'G (95% CI) in CFB		-0.51 (-2.21, 0.90)		-0.06 (-0.40, 0.27)	
p-value [3]		0.291		0.671	
					0.171

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	62	109	
Mean (StdDev)	2.7 (1.15)	3.1 (0.99)	2.3 (1.13)	2.7 (1.07)	
Median	2.0	3.0	2.0	3.0	
Min, Max	2, 4	1, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	61	109	
Mean (StdDev)	2.3 (0.58)	2.6 (1.51)	2.1 (1.23)	2.0 (1.11)	
Median	2.0	3.0	2.0	2.0	
Min, Max	2, 3	0, 4	0, 4	0, 4	
C2D1 CFB					
n	3	10	59	106	
LS Mean (StdErr) [2]	-0.61 (0.620)	-0.99 (0.549)	-0.11 (0.132)	-0.54 (0.105)	
95% CI [2]	-2.01, 0.80	-2.24, 0.25	-0.37, 0.15	-0.75, -0.33	
Difference (95% CI) in CFB [2]		-0.39 (-1.99, 1.22)		-0.43 (-0.72, -0.14)	
p-value [3]		0.598		0.004	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	10	60	100	
Mean (StdDev)	2.7 (1.53)	2.2 (1.48)	2.1 (1.17)	1.9 (1.15)	
Median	3.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	3	10	58	99	
LS Mean (StdErr) [2]	-0.39 (0.675)	-1.72 (0.597)	-0.12 (0.129)	-0.66 (0.102)	
95% CI [2]	-1.92, 1.14	-3.07, -0.37	-0.38, 0.13	-0.86, -0.46	
Difference (95% CI) in CFB [2]		-1.33 (-3.07, 0.42)		-0.54 (-0.82, -0.26)	
p-value [3]		0.120		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	2	9	54	104	
Mean (StdDev)	2.0 (0.00)	2.1 (1.54)	2.1 (1.19)	2.0 (1.15)	
Median	2.0	2.0	2.0	2.0	
Min, Max	2, 2	0, 4	0, 4	0, 4	
C4D1 CFB					
n	2	9	52	102	
LS Mean (StdErr) [2]	-0.93 (0.870)	-1.36 (0.581)	-0.13 (0.152)	-0.52 (0.118)	
95% CI [2]	-2.99, 1.12	-2.73, 0.02	-0.43, 0.17	-0.76, -0.29	
Difference (95% CI) in CFB [2]		-0.42 (-2.59, 1.75)		-0.39 (-0.72, -0.07)	
p-value [3]		0.660		0.019	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	8	57	100	
Mean (StdDev)	1.7 (0.58)	2.4 (1.30)	2.1 (1.23)	1.9 (1.16)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 2	0, 4	0, 4	0, 4	
C5D1 CFB					
n	3	8	56	96	
LS Mean (StdErr) [2]	-1.26 (0.655)	-1.10 (0.579)	-0.05 (0.150)	-0.63 (0.120)	
95% CI [2]	-2.81, 0.29	-2.47, 0.27	-0.35, 0.25	-0.87, -0.39	
Difference (95% CI) in CFB [2]		0.17 (-1.61, 1.95)		-0.58 (-0.91, -0.25)	
p-value [3]		0.831		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	55	102	
Mean (StdDev)	1.3 (0.58)	2.1 (1.17)	2.1 (1.22)	1.8 (1.26)	
Median	1.0	2.0	2.0	2.0	
Min, Max	1, 2	0, 4	0, 4	0, 4	
C6D1 CFB					
n	3	9	54	98	
LS Mean (StdErr) [2]	-1.55 (0.767)	-1.32 (0.678)	-0.15 (0.157)	-0.71 (0.123)	
95% CI [2]	-3.32, 0.22	-2.89, 0.24	-0.46, 0.16	-0.96, -0.47	
Difference (95% CI) in CFB [2]		0.22 (-1.80, 2.25)		-0.57 (-0.91, -0.22)	
p-value [3]		0.806		0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	8	55	103	
Mean (StdDev)	2.3 (1.15)	1.8 (1.28)	2.1 (1.19)	1.8 (1.26)	
Median	3.0	1.5	2.0	2.0	
Min, Max	1, 3	0, 4	0, 4	0, 4	
C7D1 CFB					
n	3	8	54	99	
LS Mean (StdErr) [2]	-0.50 (0.805)	-1.50 (0.711)	-0.09 (0.157)	-0.73 (0.121)	
95% CI [2]	-2.40, 1.40	-3.18, 0.18	-0.40, 0.22	-0.97, -0.49	
Difference (95% CI) in CFB [2]		-1.00 (-3.19, 1.19)		-0.64 (-0.98, -0.30)	
Hedges'G (95% CI) in CFB		-0.48 (-2.18, 0.93)		-0.53 (-0.88, -0.20)	
p-value [3]		0.316		<0.001	
					0.746

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	62	109	
Mean (StdDev)	2.3 (0.58)	2.4 (1.58)	2.1 (1.37)	2.1 (1.44)	
Median	2.0	3.0	2.0	2.0	
Min, Max	2, 3	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	62	109	
Mean (StdDev)	1.0 (0.00)	2.0 (1.63)	1.7 (1.42)	1.6 (1.38)	
Median	1.0	1.5	2.0	2.0	
Min, Max	1, 1	0, 4	0, 4	0, 4	
C2D1 CFB					
n	3	10	60	106	
LS Mean (StdErr) [2]	-1.29 (0.427)	-0.22 (0.377)	-0.34 (0.209)	-0.50 (0.167)	
95% CI [2]	-2.25, -0.32	-1.08, 0.63	-0.75, 0.08	-0.83, -0.17	
Difference (95% CI) in CFB [2]		1.06 (-0.04, 2.16)		-0.17 (-0.62, 0.29)	
p-value [3]		0.057		0.474	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	10	60	99	
Mean (StdDev)	1.7 (1.15)	1.6 (1.90)	1.8 (1.33)	1.6 (1.33)	
Median	1.0	0.5	2.0	1.0	
Min, Max	1, 3	0, 4	0, 4	0, 4	
C3D1 CFB					
n	3	10	58	99	
LS Mean (StdErr) [2]	-0.68 (0.706)	-0.80 (0.625)	-0.31 (0.221)	-0.55 (0.175)	
95% CI [2]	-2.28, 0.92	-2.21, 0.61	-0.75, 0.12	-0.90, -0.21	
Difference (95% CI) in CFB [2]		-0.12 (-1.95, 1.70)		-0.24 (-0.72, 0.24)	
p-value [3]		0.883		0.328	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	2	9	54	104	
Mean (StdDev)	1.0 (1.41)	1.3 (1.58)	1.9 (1.21)	1.6 (1.30)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	
C4D1 CFB					
n	2	9	52	102	
LS Mean (StdErr) [2]	-2.01 (1.071)	-1.33 (0.715)	-0.18 (0.231)	-0.58 (0.180)	
95% CI [2]	-4.55, 0.52	-3.02, 0.36	-0.64, 0.28	-0.93, -0.22	
Difference (95% CI) in CFB [2]		0.68 (-1.98, 3.35)		-0.40 (-0.89, 0.10)	
p-value [3]		0.563		0.113	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	8	56	101	
Mean (StdDev)	1.3 (0.58)	1.1 (1.46)	1.9 (1.23)	1.4 (1.30)	
Median	1.0	0.5	2.0	1.0	
Min, Max	1, 2	0, 4	0, 4	0, 4	
C5D1 CFB					
n	3	8	55	97	
LS Mean (StdErr) [2]	-0.80 (1.035)	-0.72 (0.914)	-0.11 (0.216)	-0.73 (0.171)	
95% CI [2]	-3.25, 1.65	-2.88, 1.45	-0.54, 0.31	-1.07, -0.40	
Difference (95% CI) in CFB [2]		0.08 (-2.73, 2.90)		-0.62 (-1.09, -0.15)	
p-value [3]		0.946		0.010	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	55	102	
Mean (StdDev)	1.3 (0.58)	1.4 (1.59)	2.0 (1.30)	1.5 (1.32)	
Median	1.0	1.0	2.0	1.0	
Min, Max	1, 2	0, 4	0, 4	0, 4	
C6D1 CFB					
n	3	9	54	98	
LS Mean (StdErr) [2]	-1.01 (0.610)	-0.71 (0.539)	-0.11 (0.225)	-0.60 (0.176)	
95% CI [2]	-2.42, 0.39	-1.95, 0.54	-0.55, 0.34	-0.94, -0.25	
Difference (95% CI) in CFB [2]		0.31 (-1.31, 1.92)		-0.49 (-0.98, 0.00)	
p-value [3]		0.673		0.051	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	8	55	103	
Mean (StdDev)	1.7 (0.58)	1.0 (1.41)	1.7 (1.33)	1.4 (1.31)	
Median	2.0	0.5	2.0	1.0	
Min, Max	1, 2	0, 4	0, 4	0, 4	
C7D1 CFB					
n	3	8	54	99	
LS Mean (StdErr) [2]	-0.65 (0.781)	-0.82 (0.690)	-0.18 (0.219)	-0.58 (0.169)	
95% CI [2]	-2.50, 1.19	-2.45, 0.81	-0.62, 0.25	-0.91, -0.24	
Difference (95% CI) in CFB [2]		-0.17 (-2.29, 1.96)		-0.39 (-0.86, 0.08)	
Hedges'G (95% CI) in CFB		-0.08 (-1.64, 1.43)		-0.24 (-0.58, 0.10)	
p-value [3]		0.858		0.099	
					0.907

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	62	109	
Mean (StdDev)	3.0 (1.00)	3.1 (0.99)	2.5 (1.28)	2.6 (1.32)	
Median	3.0	3.5	3.0	3.0	
Min, Max	2, 4	2, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	62	109	
Mean (StdDev)	2.3 (1.53)	2.6 (1.43)	2.3 (1.24)	2.0 (1.29)	
Median	2.0	3.0	2.0	2.0	
Min, Max	1, 4	1, 4	0, 4	0, 4	
C2D1 CFB					
n	3	10	60	106	
LS Mean (StdErr) [2]	-0.82 (0.325)	-0.84 (0.288)	-0.14 (0.173)	-0.51 (0.138)	
95% CI [2]	-1.56, -0.09	-1.49, -0.19	-0.48, 0.20	-0.79, -0.24	
Difference (95% CI) in CFB [2]		-0.02 (-0.86, 0.82)		-0.37 (-0.75, 0.00)	
p-value [3]		0.957		0.052	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	10	60	99	
Mean (StdDev)	3.0 (1.00)	2.2 (1.81)	2.3 (1.21)	1.8 (1.23)	
Median	3.0	2.5	2.0	2.0	
Min, Max	2, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	3	10	58	99	
LS Mean (StdErr) [2]	-0.14 (0.507)	-1.18 (0.448)	-0.19 (0.180)	-0.72 (0.142)	
95% CI [2]	-1.29, 1.00	-2.20, -0.17	-0.54, 0.17	-1.00, -0.44	
Difference (95% CI) in CFB [2]		-1.04 (-2.35, 0.27)		-0.53 (-0.93, -0.14)	
p-value [3]		0.106		0.008	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	2	9	54	104	
Mean (StdDev)	1.5 (2.12)	1.8 (1.48)	2.2 (1.30)	2.0 (1.34)	
Median	1.5	1.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C4D1 CFB					
n	2	9	52	102	
LS Mean (StdErr) [2]	-1.88 (0.646)	-2.04 (0.431)	-0.21 (0.194)	-0.58 (0.151)	
95% CI [2]	-3.41, -0.35	-3.06, -1.02	-0.60, 0.17	-0.87, -0.28	
Difference (95% CI) in CFB [2]		-0.16 (-1.77, 1.45)		-0.36 (-0.78, 0.05)	
p-value [3]		0.823		0.088	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	8	56	101	
Mean (StdDev)	2.0 (1.00)	1.5 (1.60)	2.2 (1.24)	1.8 (1.22)	
Median	2.0	1.0	2.0	2.0	
Min, Max	1, 3	0, 4	0, 4	0, 4	
C5D1 CFB					
n	3	8	55	97	
LS Mean (StdErr) [2]	-1.11 (0.820)	-1.78 (0.724)	-0.16 (0.187)	-0.78 (0.148)	
95% CI [2]	-3.05, 0.83	-3.49, -0.06	-0.53, 0.21	-1.07, -0.49	
Difference (95% CI) in CFB [2]		-0.67 (-2.90, 1.56)		-0.62 (-1.02, -0.21)	
p-value [3]		0.502		0.003	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	55	102	
Mean (StdDev)	2.0 (1.00)	1.8 (1.79)	2.4 (1.27)	1.7 (1.28)	
Median	2.0	1.0	2.0	2.0	
Min, Max	1, 3	0, 4	0, 4	0, 4	
C6D1 CFB					
n	3	9	54	98	
LS Mean (StdErr) [2]	-1.14 (0.551)	-1.47 (0.487)	0.03 (0.193)	-0.73 (0.151)	
95% CI [2]	-2.41, 0.13	-2.59, -0.35	-0.35, 0.42	-1.03, -0.43	
Difference (95% CI) in CFB [2]		-0.33 (-1.78, 1.13)		-0.77 (-1.19, -0.35)	
p-value [3]		0.616		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	8	55	103	
Mean (StdDev)	2.7 (1.53)	1.5 (1.60)	2.2 (1.27)	1.8 (1.36)	
Median	3.0	1.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	3	8	54	99	
LS Mean (StdErr) [2]	-0.60 (0.587)	-1.85 (0.518)	-0.23 (0.208)	-0.76 (0.160)	
95% CI [2]	-1.99, 0.78	-3.08, -0.63	-0.64, 0.18	-1.08, -0.44	
Difference (95% CI) in CFB [2]		-1.25 (-2.85, 0.35)		-0.53 (-0.98, -0.09)	
Hedges'G (95% CI) in CFB		-0.83 (-2.66, 0.53)		-0.34 (-0.68, -0.00)	
p-value [3]		0.106		0.020	
					0.569

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	62	109	
Mean (StdDev)	1.7 (1.53)	3.0 (0.82)	2.3 (1.37)	2.4 (1.10)	
Median	2.0	3.0	3.0	2.0	
Min, Max	0, 3	2, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	62	109	
Mean (StdDev)	1.7 (0.58)	2.1 (1.10)	2.1 (1.21)	1.8 (1.22)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 2	0, 4	0, 4	0, 4	
C2D1 CFB					
n	3	10	60	106	
LS Mean (StdErr) [2]	-0.11 (0.630)	-1.21 (0.557)	-0.13 (0.170)	-0.48 (0.136)	
95% CI [2]	-1.53, 1.32	-2.47, 0.05	-0.47, 0.20	-0.75, -0.22	
Difference (95% CI) in CFB [2]		-1.10 (-2.73, 0.53)		-0.35 (-0.72, 0.02)	
p-value [3]		0.160		0.064	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-thpy-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	10	60	99	
Mean (StdDev)	1.3 (0.58)	2.1 (0.99)	2.0 (1.41)	1.7 (1.13)	
Median	1.0	2.0	2.0	2.0	
Min, Max	1, 2	1, 4	0, 4	0, 4	
C3D1 CFB					
n	3	10	58	99	
LS Mean (StdErr) [2]	-0.25 (0.595)	-0.82 (0.526)	-0.23 (0.163)	-0.54 (0.129)	
95% CI [2]	-1.60, 1.10	-2.01, 0.37	-0.56, 0.09	-0.80, -0.29	
Difference (95% CI) in CFB [2]		-0.57 (-2.11, 0.97)		-0.31 (-0.66, 0.05)	
p-value [3]		0.423		0.089	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	2	9	54	104	
Mean (StdDev)	1.5 (0.71)	1.6 (1.33)	2.1 (1.36)	1.8 (1.21)	
Median	1.5	1.0	2.0	2.0	
Min, Max	1, 2	0, 4	0, 4	0, 4	
C4D1 CFB					
n	2	9	52	102	
LS Mean (StdErr) [2]	-1.20 (0.740)	-1.93 (0.494)	-0.24 (0.197)	-0.61 (0.153)	
95% CI [2]	-2.95, 0.55	-3.10, -0.77	-0.62, 0.15	-0.91, -0.30	
Difference (95% CI) in CFB [2]		-0.74 (-2.58, 1.10)		-0.37 (-0.79, 0.05)	
p-value [3]		0.376		0.084	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	8	56	101	
Mean (StdDev)	1.0 (1.00)	1.8 (1.28)	2.1 (1.32)	1.6 (1.24)	
Median	1.0	1.5	2.0	2.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	
C5D1 CFB					
n	3	8	55	97	
LS Mean (StdErr) [2]	-0.59 (0.622)	-1.01 (0.549)	-0.12 (0.196)	-0.78 (0.155)	
95% CI [2]	-2.06, 0.88	-2.31, 0.29	-0.51, 0.27	-1.08, -0.47	
Difference (95% CI) in CFB [2]		-0.42 (-2.11, 1.27)		-0.66 (-1.08, -0.23)	
p-value [3]		0.578		0.003	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	55	102	
Mean (StdDev)	1.7 (0.58)	1.6 (1.42)	2.3 (1.35)	1.6 (1.23)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 2	0, 4	0, 4	0, 4	
C6D1 CFB					
n	3	9	54	98	
LS Mean (StdErr) [2]	0.09 (0.773)	-1.21 (0.683)	0.11 (0.196)	-0.73 (0.153)	
95% CI [2]	-1.69, 1.87	-2.78, 0.37	-0.28, 0.49	-1.03, -0.42	
Difference (95% CI) in CFB [2]		-1.29 (-3.34, 0.75)		-0.83 (-1.26, -0.41)	
p-value [3]		0.182		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	8	55	103	
Mean (StdDev)	1.7 (0.58)	1.1 (1.36)	2.0 (1.35)	1.7 (1.28)	
Median	2.0	1.0	2.0	2.0	
Min, Max	1, 2	0, 4	0, 4	0, 4	
C7D1 CFB					
n	3	8	54	99	
LS Mean (StdErr) [2]	-0.01 (0.567)	-1.85 (0.501)	-0.08 (0.195)	-0.62 (0.150)	
95% CI [2]	-1.35, 1.33	-3.03, -0.66	-0.47, 0.30	-0.92, -0.32	
Difference (95% CI) in CFB [2]		-1.83 (-3.37, -0.29)		-0.54 (-0.96, -0.12)	
Hedges'G (95% CI) in CFB		-1.26 (-3.30, 0.07)		-0.36 (-0.71, -0.03)	
p-value [3]		0.026		0.012	
					0.182

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	62	109	
Mean (StdDev)	1.7 (1.53)	2.1 (1.73)	1.7 (1.54)	1.9 (1.48)	
Median	2.0	2.5	1.5	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	62	109	
Mean (StdDev)	0.7 (0.58)	1.8 (1.93)	1.8 (1.52)	1.6 (1.42)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 1	0, 4	0, 4	0, 4	
C2D1 CFB					
n	3	10	60	106	
LS Mean (StdErr) [2]	-1.29 (0.811)	-0.94 (0.718)	0.03 (0.159)	-0.30 (0.127)	
95% CI [2]	-3.12, 0.55	-2.56, 0.68	-0.28, 0.35	-0.55, -0.05	
Difference (95% CI) in CFB [2]		0.35 (-1.75, 2.44)		-0.34 (-0.68, 0.01)	
p-value [3]		0.717		0.056	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	10	60	99	
Mean (StdDev)	0.7 (1.15)	1.8 (1.48)	1.6 (1.57)	1.3 (1.41)	
Median	0.0	1.5	1.0	1.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	
C3D1 CFB					
n	3	10	58	99	
LS Mean (StdErr) [2]	-0.93 (0.788)	-0.19 (0.697)	-0.19 (0.165)	-0.47 (0.130)	
95% CI [2]	-2.71, 0.85	-1.77, 1.38	-0.51, 0.14	-0.72, -0.21	
Difference (95% CI) in CFB [2]		0.73 (-1.30, 2.77)		-0.28 (-0.64, 0.08)	
p-value [3]		0.436		0.131	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	2	9	54	104	
Mean (StdDev)	1.5 (0.71)	1.0 (1.50)	1.6 (1.37)	1.4 (1.39)	
Median	1.5	0.0	1.0	1.0	
Min, Max	1, 2	0, 4	0, 4	0, 4	
C4D1 CFB					
n	2	9	52	102	
LS Mean (StdErr) [2]	-1.41 (1.302)	-1.20 (0.869)	-0.15 (0.202)	-0.36 (0.157)	
95% CI [2]	-4.49, 1.67	-3.25, 0.86	-0.55, 0.24	-0.67, -0.05	
Difference (95% CI) in CFB [2]		0.21 (-3.03, 3.45)		-0.20 (-0.63, 0.23)	
p-value [3]		0.882		0.357	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-thpy-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	8	56	100	
Mean (StdDev)	0.0 (0.00)	1.0 (1.31)	1.5 (1.41)	1.4 (1.38)	
Median	0.0	0.5	1.0	1.0	
Min, Max	0, 0	0, 3	0, 4	0, 4	
C5D1 CFB					
n	3	8	55	96	
LS Mean (StdErr) [2]	-1.52 (0.850)	-0.77 (0.751)	-0.15 (0.203)	-0.47 (0.161)	
95% CI [2]	-3.53, 0.49	-2.55, 1.00	-0.56, 0.25	-0.79, -0.15	
Difference (95% CI) in CFB [2]		0.75 (-1.56, 3.06)		-0.31 (-0.76, 0.13)	
p-value [3]		0.468		0.165	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	55	102	
Mean (StdDev)	0.3 (0.58)	1.1 (1.54)	1.5 (1.40)	1.4 (1.45)	
Median	0.0	0.0	1.0	1.0	
Min, Max	0, 1	0, 4	0, 4	0, 4	
C6D1 CFB					
n	3	9	54	98	
LS Mean (StdErr) [2]	-1.48 (0.801)	-1.09 (0.708)	-0.23 (0.222)	-0.48 (0.173)	
95% CI [2]	-3.32, 0.37	-2.72, 0.54	-0.66, 0.21	-0.82, -0.14	
Difference (95% CI) in CFB [2]		0.39 (-1.73, 2.50)		-0.25 (-0.74, 0.23)	
p-value [3]		0.683		0.299	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	8	55	103	
Mean (StdDev)	1.0 (0.00)	0.5 (1.07)	1.5 (1.45)	1.4 (1.44)	
Median	1.0	0.0	1.0	1.0	
Min, Max	1, 1	0, 3	0, 4	0, 4	
C7D1 CFB					
n	3	8	54	99	
LS Mean (StdErr) [2]	-0.54 (0.915)	-1.04 (0.808)	-0.04 (0.212)	-0.34 (0.163)	
95% CI [2]	-2.71, 1.62	-2.95, 0.87	-0.45, 0.38	-0.66, -0.02	
Difference (95% CI) in CFB [2]		-0.50 (-2.99, 1.99)		-0.31 (-0.76, 0.15)	
Hedges'G (95% CI) in CFB		-0.21 (-1.81, 1.26)		-0.19 (-0.53, 0.14)	
p-value [3]		0.649		0.184	
					0.784

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	62	109	
Mean (StdDev)	2.7 (0.58)	2.9 (0.88)	2.1 (1.34)	2.3 (1.19)	
Median	3.0	3.0	2.0	2.0	
Min, Max	2, 3	2, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	62	109	
Mean (StdDev)	2.0 (1.00)	2.3 (1.34)	1.8 (1.26)	1.8 (1.15)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 3	0, 4	0, 4	0, 4	
C2D1 CFB					
n	3	10	60	106	
LS Mean (StdErr) [2]	-0.86 (0.541)	-0.96 (0.478)	-0.28 (0.135)	-0.42 (0.108)	
95% CI [2]	-2.08, 0.37	-2.04, 0.12	-0.54, -0.01	-0.63, -0.20	
Difference (95% CI) in CFB [2]		-0.10 (-1.50, 1.30)		-0.14 (-0.43, 0.15)	
p-value [3]		0.873		0.350	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	10	60	99	
Mean (StdDev)	2.7 (1.53)	2.3 (1.49)	1.9 (1.28)	1.6 (1.25)	
Median	3.0	2.5	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	3	10	58	99	
LS Mean (StdErr) [2]	-0.04 (0.588)	-0.69 (0.520)	-0.22 (0.156)	-0.72 (0.123)	
95% CI [2]	-1.37, 1.29	-1.87, 0.49	-0.53, 0.09	-0.97, -0.48	
Difference (95% CI) in CFB [2]		-0.65 (-2.17, 0.87)		-0.50 (-0.85, -0.16)	
p-value [3]		0.356		0.004	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	2	9	54	104	
Mean (StdDev)	1.5 (2.12)	1.6 (1.67)	1.9 (1.14)	1.6 (1.14)	
Median	1.5	1.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C4D1 CFB					
n	2	9	52	102	
LS Mean (StdErr) [2]	-1.55 (0.938)	-1.82 (0.626)	-0.23 (0.152)	-0.68 (0.118)	
95% CI [2]	-3.77, 0.66	-3.30, -0.34	-0.53, 0.07	-0.91, -0.45	
Difference (95% CI) in CFB [2]		-0.26 (-2.60, 2.07)		-0.45 (-0.78, -0.13)	
p-value [3]		0.798		0.007	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	8	56	101	
Mean (StdDev)	1.3 (0.58)	1.6 (1.51)	1.8 (1.24)	1.5 (1.22)	
Median	1.0	2.0	2.0	1.0	
Min, Max	1, 2	0, 4	0, 4	0, 4	
C5D1 CFB					
n	3	8	55	97	
LS Mean (StdErr) [2]	-1.23 (0.587)	-0.98 (0.518)	-0.31 (0.164)	-0.87 (0.130)	
95% CI [2]	-2.62, 0.16	-2.21, 0.25	-0.64, 0.01	-1.12, -0.61	
Difference (95% CI) in CFB [2]		0.25 (-1.35, 1.85)		-0.55 (-0.91, -0.19)	
p-value [3]		0.722		0.003	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	55	102	
Mean (StdDev)	1.7 (0.58)	2.1 (1.69)	2.1 (1.24)	1.5 (1.31)	
Median	2.0	2.0	2.0	1.0	
Min, Max	1, 2	0, 4	0, 4	0, 4	
C6D1 CFB					
n	3	9	54	98	
LS Mean (StdErr) [2]	-0.98 (0.673)	-0.59 (0.595)	0.02 (0.173)	-0.80 (0.135)	
95% CI [2]	-2.53, 0.58	-1.96, 0.78	-0.32, 0.37	-1.07, -0.53	
Difference (95% CI) in CFB [2]		0.39 (-1.39, 2.17)		-0.83 (-1.20, -0.45)	
p-value [3]		0.628		<0.0001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	8	55	103	
Mean (StdDev)	1.7 (0.58)	1.3 (1.28)	1.9 (1.40)	1.5 (1.35)	
Median	2.0	1.0	2.0	1.0	
Min, Max	1, 2	0, 3	0, 4	0, 4	
C7D1 CFB					
n	3	8	54	99	
LS Mean (StdErr) [2]	-0.97 (0.452)	-1.31 (0.399)	-0.08 (0.169)	-0.72 (0.130)	
95% CI [2]	-2.04, 0.10	-2.25, -0.36	-0.42, 0.25	-0.98, -0.46	
Difference (95% CI) in CFB [2]		-0.33 (-1.56, 0.90)		-0.64 (-1.00, -0.27)	
Hedges'G (95% CI) in CFB		-0.29 (-1.91, 1.17)		-0.49 (-0.84, -0.16)	
p-value [3]		0.542		<0.001	
					0.701

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	62	109	
Mean (StdDev)	2.3 (1.15)	2.9 (1.20)	1.9 (1.41)	2.1 (1.29)	
Median	3.0	3.0	2.0	2.0	
Min, Max	1, 3	1, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	62	109	
Mean (StdDev)	1.0 (1.00)	2.2 (1.48)	1.5 (1.22)	1.6 (1.25)	
Median	1.0	2.0	1.0	1.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	
C2D1 CFB					
n	3	10	60	106	
LS Mean (StdErr) [2]	-1.61 (0.351)	-1.28 (0.310)	-0.33 (0.154)	-0.43 (0.123)	
95% CI [2]	-2.40, -0.81	-1.98, -0.58	-0.63, -0.02	-0.67, -0.19	
Difference (95% CI) in CFB [2]		0.33 (-0.58, 1.23)		-0.10 (-0.44, 0.23)	
p-value [3]		0.436		0.538	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-thpy-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	10	60	99	
Mean (StdDev)	1.3 (0.58)	2.1 (1.52)	1.6 (1.31)	1.4 (1.25)	
Median	1.0	2.5	1.0	1.0	
Min, Max	1, 2	0, 4	0, 4	0, 4	
C3D1 CFB					
n	3	10	58	99	
LS Mean (StdErr) [2]	-0.96 (0.557)	-0.74 (0.492)	-0.27 (0.160)	-0.63 (0.126)	
95% CI [2]	-2.22, 0.30	-1.85, 0.37	-0.59, 0.04	-0.88, -0.38	
Difference (95% CI) in CFB [2]		0.22 (-1.21, 1.66)		-0.35 (-0.70, -0.00)	
p-value [3]		0.732		0.048	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	2	9	54	104	
Mean (StdDev)	1.5 (0.71)	1.4 (1.74)	1.6 (1.17)	1.4 (1.22)	
Median	1.5	1.0	2.0	1.0	
Min, Max	1, 2	0, 4	0, 4	0, 4	
C4D1 CFB					
n	2	9	52	102	
LS Mean (StdErr) [2]	-2.61 (0.538)	-2.13 (0.359)	-0.35 (0.161)	-0.67 (0.125)	
95% CI [2]	-3.88, -1.33	-2.98, -1.28	-0.67, -0.04	-0.92, -0.42	
Difference (95% CI) in CFB [2]		0.47 (-0.87, 1.81)		-0.32 (-0.66, 0.03)	
p-value [3]		0.431		0.071	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	8	56	101	
Mean (StdDev)	1.3 (1.15)	1.4 (1.51)	1.6 (1.32)	1.4 (1.21)	
Median	2.0	1.0	1.0	1.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	
C5D1 CFB					
n	3	8	55	97	
LS Mean (StdErr) [2]	-1.21 (0.435)	-1.71 (0.384)	-0.26 (0.172)	-0.70 (0.136)	
95% CI [2]	-2.24, -0.18	-2.62, -0.80	-0.61, 0.08	-0.97, -0.43	
Difference (95% CI) in CFB [2]		-0.50 (-1.68, 0.68)		-0.44 (-0.81, -0.06)	
p-value [3]		0.351		0.023	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	55	102	
Mean (StdDev)	1.7 (1.15)	1.6 (1.67)	1.7 (1.27)	1.4 (1.33)	
Median	1.0	2.0	2.0	1.0	
Min, Max	1, 3	0, 4	0, 4	0, 4	
C6D1 CFB					
n	3	9	54	98	
LS Mean (StdErr) [2]	-0.78 (0.806)	-1.44 (0.712)	-0.19 (0.175)	-0.75 (0.137)	
95% CI [2]	-2.64, 1.08	-3.08, 0.20	-0.54, 0.15	-1.02, -0.48	
Difference (95% CI) in CFB [2]		-0.66 (-2.79, 1.47)		-0.55 (-0.93, -0.17)	
p-value [3]		0.496		0.005	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	8	55	103	
Mean (StdDev)	2.0 (1.00)	1.0 (1.20)	1.5 (1.35)	1.3 (1.37)	
Median	2.0	0.5	2.0	1.0	
Min, Max	1, 3	0, 3	0, 4	0, 4	
C7D1 CFB					
n	3	8	54	99	
LS Mean (StdErr) [2]	-0.42 (0.729)	-1.84 (0.643)	-0.15 (0.175)	-0.62 (0.135)	
95% CI [2]	-2.15, 1.30	-3.36, -0.32	-0.50, 0.19	-0.89, -0.36	
Difference (95% CI) in CFB [2]		-1.42 (-3.40, 0.56)		-0.47 (-0.85, -0.10)	
Hedges'G (95% CI) in CFB		-0.76 (-2.56, 0.62)		-0.35 (-0.70, -0.02)	
p-value [3]		0.135		0.014	
					0.332

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	62	109	
Mean (StdDev)	2.7 (0.58)	3.0 (1.15)	3.0 (0.93)	2.9 (1.00)	
Median	3.0	3.0	3.0	3.0	
Min, Max	2, 3	1, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	62	109	
Mean (StdDev)	2.3 (0.58)	2.8 (0.92)	2.5 (1.10)	2.5 (1.02)	
Median	2.0	3.0	3.0	2.0	
Min, Max	2, 3	1, 4	0, 4	0, 4	
C2D1 CFB					
n	3	10	60	106	
LS Mean (StdErr) [2]	-0.29 (0.580)	-0.08 (0.513)	-0.52 (0.136)	-0.49 (0.109)	
95% CI [2]	-1.60, 1.03	-1.24, 1.08	-0.79, -0.25	-0.70, -0.28	
Difference (95% CI) in CFB [2]		0.20 (-1.30, 1.70)		0.03 (-0.27, 0.33)	
p-value [3]		0.765		0.840	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	10	60	99	
Mean (StdDev)	2.0 (1.00)	2.2 (1.14)	2.6 (1.06)	2.2 (1.14)	
Median	2.0	2.0	3.0	2.0	
Min, Max	1, 3	0, 4	0, 4	0, 4	
C3D1 CFB					
n	3	10	58	99	
LS Mean (StdErr) [2]	-0.79 (0.454)	-1.01 (0.401)	-0.31 (0.146)	-0.57 (0.116)	
95% CI [2]	-1.81, 0.24	-1.92, -0.10	-0.60, -0.02	-0.80, -0.34	
Difference (95% CI) in CFB [2]		-0.22 (-1.40, 0.95)		-0.26 (-0.58, 0.06)	
p-value [3]		0.675		0.111	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	2	9	54	104	
Mean (StdDev)	2.0 (0.00)	2.0 (1.32)	2.4 (1.24)	2.4 (1.20)	
Median	2.0	2.0	3.0	2.0	
Min, Max	2, 2	0, 4	0, 4	0, 4	
C4D1 CFB					
n	2	9	52	102	
LS Mean (StdErr) [2]	-1.08 (0.283)	-0.97 (0.189)	-0.56 (0.166)	-0.48 (0.129)	
95% CI [2]	-1.75, -0.41	-1.42, -0.53	-0.89, -0.23	-0.73, -0.22	
Difference (95% CI) in CFB [2]		0.11 (-0.60, 0.81)		0.08 (-0.27, 0.44)	
p-value [3]		0.734		0.648	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	8	57	101	
Mean (StdDev)	2.0 (0.00)	2.1 (0.99)	2.6 (1.05)	2.0 (1.30)	
Median	2.0	2.0	3.0	2.0	
Min, Max	2, 2	1, 4	0, 4	0, 4	
C5D1 CFB					
n	3	8	56	97	
LS Mean (StdErr) [2]	-0.47 (0.528)	-0.38 (0.466)	-0.45 (0.175)	-0.94 (0.138)	
95% CI [2]	-1.71, 0.78	-1.48, 0.72	-0.79, -0.10	-1.21, -0.67	
Difference (95% CI) in CFB [2]		0.08 (-1.35, 1.52)		-0.49 (-0.87, -0.11)	
p-value [3]		0.895		0.011	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	55	102	
Mean (StdDev)	2.0 (0.00)	1.8 (1.30)	2.6 (1.23)	2.2 (1.23)	
Median	2.0	1.0	3.0	2.0	
Min, Max	2, 2	0, 4	0, 4	0, 4	
C6D1 CFB					
n	3	9	54	98	
LS Mean (StdErr) [2]	-0.60 (0.495)	-1.00 (0.437)	-0.22 (0.183)	-0.59 (0.143)	
95% CI [2]	-1.74, 0.54	-2.01, 0.01	-0.58, 0.15	-0.87, -0.31	
Difference (95% CI) in CFB [2]		-0.40 (-1.71, 0.91)		-0.37 (-0.77, 0.03)	
p-value [3]		0.500		0.067	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-thpy-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	8	55	103	
Mean (StdDev)	2.0 (0.00)	1.6 (1.41)	2.5 (1.14)	2.2 (1.18)	
Median	2.0	1.5	3.0	2.0	
Min, Max	2, 2	0, 4	0, 4	0, 4	
C7D1 CFB					
n	3	8	54	99	
LS Mean (StdErr) [2]	-0.71 (0.545)	-1.21 (0.482)	-0.29 (0.169)	-0.62 (0.130)	
95% CI [2]	-2.00, 0.58	-2.35, -0.07	-0.63, 0.04	-0.88, -0.37	
Difference (95% CI) in CFB [2]		-0.50 (-1.98, 0.98)		-0.33 (-0.69, 0.03)	
Hedges'G (95% CI) in CFB		-0.36 (-2.00, 1.09)		-0.26 (-0.60, 0.07)	
p-value [3]		0.451		0.074	
					0.905

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-thpy-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	62	109	
Mean (StdDev)	2.3 (1.53)	2.1 (1.37)	2.5 (1.47)	2.5 (1.21)	
Median	2.0	2.0	3.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	62	109	
Mean (StdDev)	2.3 (2.08)	2.4 (1.26)	2.2 (1.19)	1.9 (1.37)	
Median	3.0	2.5	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	3	10	60	106	
LS Mean (StdErr) [2]	-0.25 (0.520)	-0.25 (0.460)	-0.26 (0.156)	-0.54 (0.125)	
95% CI [2]	-1.43, 0.93	-1.29, 0.79	-0.57, 0.05	-0.79, -0.29	
Difference (95% CI) in CFB [2]		0.00 (-1.35, 1.35)		-0.28 (-0.62, 0.06)	
p-value [3]		>0.999		0.107	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-thpy-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	10	60	99	
Mean (StdDev)	2.3 (1.15)	2.0 (1.63)	2.3 (1.22)	1.8 (1.25)	
Median	3.0	2.0	2.0	2.0	
Min, Max	1, 3	0, 4	0, 4	0, 4	
C3D1 CFB					
n	3	10	58	99	
LS Mean (StdErr) [2]	-0.32 (0.715)	-0.77 (0.632)	-0.19 (0.173)	-0.70 (0.137)	
95% CI [2]	-1.94, 1.30	-2.20, 0.66	-0.53, 0.15	-0.97, -0.43	
Difference (95% CI) in CFB [2]		-0.45 (-2.30, 1.40)		-0.51 (-0.89, -0.14)	
p-value [3]		0.596		0.008	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-thpy-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	2	9	54	104	
Mean (StdDev)	2.0 (1.41)	1.8 (1.64)	2.1 (1.31)	1.8 (1.40)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 3	0, 4	0, 4	0, 4	
C4D1 CFB					
n	2	9	52	102	
LS Mean (StdErr) [2]	0.41 (0.421)	-0.80 (0.281)	-0.43 (0.173)	-0.64 (0.135)	
95% CI [2]	-0.59, 1.40	-1.47, -0.14	-0.77, -0.09	-0.90, -0.37	
Difference (95% CI) in CFB [2]		-1.21 (-2.26, -0.16)		-0.21 (-0.58, 0.16)	
p-value [3]		0.029		0.270	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	8	57	101	
Mean (StdDev)	2.7 (1.53)	1.6 (1.30)	1.9 (1.47)	1.8 (1.47)	
Median	3.0	1.5	2.0	2.0	
Min, Max	1, 4	0, 3	0, 4	0, 4	
C5D1 CFB					
n	3	8	56	97	
LS Mean (StdErr) [2]	0.25 (0.329)	-0.75 (0.290)	-0.43 (0.176)	-0.73 (0.139)	
95% CI [2]	-0.53, 1.03	-1.44, -0.06	-0.77, -0.08	-1.01, -0.46	
Difference (95% CI) in CFB [2]		-1.00 (-1.89, -0.11)		-0.31 (-0.69, 0.08)	
p-value [3]		0.033		0.116	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-thpy-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	55	102	
Mean (StdDev)	2.3 (1.15)	1.6 (1.33)	2.2 (1.32)	1.6 (1.40)	
Median	3.0	1.0	2.0	2.0	
Min, Max	1, 3	0, 4	0, 4	0, 4	
C6D1 CFB					
n	3	9	54	98	
LS Mean (StdErr) [2]	-0.09 (0.357)	-0.79 (0.315)	-0.11 (0.182)	-0.81 (0.143)	
95% CI [2]	-0.91, 0.73	-1.52, -0.07	-0.47, 0.25	-1.09, -0.52	
Difference (95% CI) in CFB [2]		-0.71 (-1.65, 0.24)		-0.70 (-1.10, -0.30)	
p-value [3]		0.123		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	8	55	103	
Mean (StdDev)	2.3 (2.08)	1.3 (1.58)	2.0 (1.41)	1.5 (1.41)	
Median	3.0	0.5	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	3	8	54	99	
LS Mean (StdErr) [2]	-0.20 (0.561)	-1.28 (0.495)	-0.32 (0.188)	-0.78 (0.145)	
95% CI [2]	-1.53, 1.13	-2.46, -0.11	-0.69, 0.05	-1.07, -0.49	
Difference (95% CI) in CFB [2]		-1.08 (-2.61, 0.44)		-0.46 (-0.86, -0.05)	
Hedges'G (95% CI) in CFB		-0.75 (-2.55, 0.62)		-0.32 (-0.66, 0.01)	
p-value [3]		0.137		0.027	
					0.623

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-thpy-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	62	109	
Mean (StdDev)	2.7 (0.58)	3.0 (0.94)	2.8 (1.16)	3.0 (0.97)	
Median	3.0	3.0	3.0	3.0	
Min, Max	2, 3	1, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	62	109	
Mean (StdDev)	2.3 (0.58)	2.3 (1.49)	2.2 (1.15)	2.3 (1.22)	
Median	2.0	2.0	2.0	2.0	
Min, Max	2, 3	0, 4	0, 4	0, 4	
C2D1 CFB					
n	3	10	60	106	
LS Mean (StdErr) [2]	-0.64 (0.402)	-1.40 (0.356)	-0.59 (0.148)	-0.72 (0.119)	
95% CI [2]	-1.55, 0.27	-2.20, -0.59	-0.88, -0.30	-0.96, -0.49	
Difference (95% CI) in CFB [2]		-0.76 (-1.79, 0.28)		-0.13 (-0.46, 0.19)	
p-value [3]		0.135		0.418	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	10	60	99	
Mean (StdDev)	3.0 (1.00)	2.4 (1.26)	2.4 (1.22)	2.0 (1.22)	
Median	3.0	2.5	2.0	2.0	
Min, Max	2, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	3	10	58	99	
LS Mean (StdErr) [2]	0.32 (0.522)	-0.66 (0.462)	-0.43 (0.164)	-0.96 (0.130)	
95% CI [2]	-0.86, 1.50	-1.70, 0.39	-0.76, -0.11	-1.22, -0.71	
Difference (95% CI) in CFB [2]		-0.98 (-2.33, 0.37)		-0.53 (-0.89, -0.17)	
p-value [3]		0.135		0.004	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-thpy-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	2	9	54	104	
Mean (StdDev)	2.0 (0.00)	2.0 (1.12)	2.5 (1.19)	2.1 (1.25)	
Median	2.0	2.0	2.0	2.0	
Min, Max	2, 2	1, 4	0, 4	0, 4	
C4D1 CFB					
n	2	9	52	102	
LS Mean (StdErr) [2]	-0.88 (0.779)	-1.04 (0.520)	-0.34 (0.167)	-0.94 (0.130)	
95% CI [2]	-2.72, 0.96	-2.27, 0.19	-0.67, -0.01	-1.20, -0.68	
Difference (95% CI) in CFB [2]		-0.16 (-2.10, 1.78)		-0.60 (-0.96, -0.24)	
p-value [3]		0.853		0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	8	57	100	
Mean (StdDev)	2.3 (0.58)	2.1 (0.99)	2.3 (1.21)	2.0 (1.22)	
Median	2.0	2.0	2.0	2.0	
Min, Max	2, 3	1, 4	0, 4	0, 4	
C5D1 CFB					
n	3	8	56	96	
LS Mean (StdErr) [2]	-0.42 (0.454)	-0.84 (0.401)	-0.45 (0.166)	-1.02 (0.131)	
95% CI [2]	-1.50, 0.65	-1.79, 0.11	-0.77, -0.12	-1.28, -0.76	
Difference (95% CI) in CFB [2]		-0.42 (-1.65, 0.82)		-0.57 (-0.93, -0.21)	
p-value [3]		0.451		0.002	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	55	102	
Mean (StdDev)	2.0 (0.00)	1.8 (1.39)	2.5 (1.18)	1.9 (1.31)	
Median	2.0	1.0	3.0	2.0	
Min, Max	2, 2	0, 4	0, 4	0, 4	
C6D1 CFB					
n	3	9	54	98	
LS Mean (StdErr) [2]	-0.94 (0.724)	-1.62 (0.640)	-0.30 (0.172)	-1.10 (0.135)	
95% CI [2]	-2.61, 0.74	-3.09, -0.14	-0.64, 0.04	-1.37, -0.84	
Difference (95% CI) in CFB [2]		-0.68 (-2.60, 1.23)		-0.80 (-1.18, -0.43)	
p-value [3]		0.435		<0.0001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	8	55	103	
Mean (StdDev)	2.3 (1.53)	1.5 (1.31)	2.2 (1.33)	1.9 (1.33)	
Median	2.0	1.5	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	3	8	54	99	
LS Mean (StdErr) [2]	-0.42 (0.805)	-1.42 (0.711)	-0.37 (0.173)	-0.93 (0.133)	
95% CI [2]	-2.32, 1.49	-3.10, 0.27	-0.71, -0.03	-1.19, -0.67	
Difference (95% CI) in CFB [2]		-1.00 (-3.19, 1.19)		-0.56 (-0.93, -0.19)	
Hedges'G (95% CI) in CFB		-0.48 (-2.18, 0.93)		-0.42 (-0.77, -0.09)	
p-value [3]		0.316		0.003	
					0.697

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	62	109	
Mean (StdDev)	3.3 (0.58)	3.7 (0.48)	3.1 (0.94)	3.1 (0.95)	
Median	3.0	4.0	3.0	3.0	
Min, Max	3, 4	3, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	62	109	
Mean (StdDev)	2.7 (0.58)	2.7 (0.95)	2.6 (1.01)	2.3 (1.09)	
Median	3.0	2.0	3.0	2.0	
Min, Max	2, 3	2, 4	0, 4	0, 4	
C2D1 CFB					
n	3	10	60	106	
LS Mean (StdErr) [2]	-0.86 (0.632)	-1.39 (0.559)	-0.40 (0.132)	-0.74 (0.105)	
95% CI [2]	-2.29, 0.57	-2.65, -0.12	-0.66, -0.14	-0.95, -0.53	
Difference (95% CI) in CFB [2]		-0.53 (-2.17, 1.10)		-0.34 (-0.63, -0.05)	
p-value [3]		0.481		0.021	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	10	60	99	
Mean (StdDev)	2.7 (0.58)	2.6 (0.97)	2.5 (1.11)	2.1 (1.18)	
Median	3.0	2.5	3.0	2.0	
Min, Max	2, 3	1, 4	0, 4	0, 4	
C3D1 CFB					
n	3	10	58	99	
LS Mean (StdErr) [2]	-0.61 (0.684)	-0.99 (0.605)	-0.55 (0.155)	-0.99 (0.122)	
95% CI [2]	-2.15, 0.94	-2.36, 0.37	-0.86, -0.24	-1.23, -0.75	
Difference (95% CI) in CFB [2]		-0.39 (-2.16, 1.38)		-0.44 (-0.78, -0.10)	
p-value [3]		0.632		0.011	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	2	9	54	104	
Mean (StdDev)	3.0 (1.41)	2.2 (0.83)	2.4 (1.14)	2.1 (1.17)	
Median	3.0	2.0	2.0	2.0	
Min, Max	2, 4	1, 4	0, 4	0, 4	
C4D1 CFB					
n	2	9	52	102	
LS Mean (StdErr) [2]	-0.49 (0.760)	-1.17 (0.507)	-0.66 (0.156)	-1.07 (0.121)	
95% CI [2]	-2.28, 1.31	-2.37, 0.03	-0.97, -0.35	-1.30, -0.83	
Difference (95% CI) in CFB [2]		-0.68 (-2.58, 1.21)		-0.40 (-0.74, -0.07)	
p-value [3]		0.421		0.018	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	8	57	101	
Mean (StdDev)	2.7 (1.15)	2.0 (1.20)	2.4 (1.29)	2.2 (1.19)	
Median	2.0	2.0	3.0	2.0	
Min, Max	2, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	3	8	56	97	
LS Mean (StdErr) [2]	-0.48 (0.850)	-1.23 (0.751)	-0.54 (0.169)	-0.94 (0.134)	
95% CI [2]	-2.49, 1.53	-3.00, 0.55	-0.87, -0.20	-1.21, -0.68	
Difference (95% CI) in CFB [2]		-0.75 (-3.06, 1.56)		-0.41 (-0.77, -0.04)	
p-value [3]		0.468		0.030	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	55	102	
Mean (StdDev)	2.7 (1.15)	1.9 (1.27)	2.6 (1.16)	2.0 (1.29)	
Median	2.0	1.0	3.0	2.0	
Min, Max	2, 4	1, 4	0, 4	0, 4	
C6D1 CFB					
n	3	9	54	98	
LS Mean (StdErr) [2]	-0.69 (0.918)	-1.79 (0.811)	-0.42 (0.175)	-1.06 (0.137)	
95% CI [2]	-2.81, 1.43	-3.67, 0.08	-0.77, -0.08	-1.33, -0.79	
Difference (95% CI) in CFB [2]		-1.11 (-3.53, 1.32)		-0.64 (-1.02, -0.26)	
p-value [3]		0.324		0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	8	55	103	
Mean (StdDev)	3.3 (0.58)	1.5 (0.93)	2.3 (1.34)	2.0 (1.29)	
Median	3.0	1.5	3.0	2.0	
Min, Max	3, 4	0, 3	0, 4	0, 4	
C7D1 CFB					
n	3	8	54	99	
LS Mean (StdErr) [2]	0.05 (0.765)	-2.03 (0.675)	-0.54 (0.178)	-0.99 (0.137)	
95% CI [2]	-1.76, 1.86	-3.63, -0.44	-0.89, -0.19	-1.27, -0.72	
Difference (95% CI) in CFB [2]		-2.08 (-4.16, -0.00)		-0.45 (-0.83, -0.07)	
Hedges'G (95% CI) in CFB		-1.06 (-3.00, 0.28)		-0.33 (-0.68, -0.00)	
p-value [3]		0.050		0.021	
					0.043

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	62	109	
Mean (StdDev)	3.0 (1.00)	2.7 (1.49)	2.3 (1.46)	1.8 (1.47)	
Median	3.0	3.0	3.0	2.0	
Min, Max	2, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	62	109	
Mean (StdDev)	2.3 (0.58)	2.3 (1.42)	2.0 (1.45)	1.4 (1.40)	
Median	2.0	2.5	2.0	1.0	
Min, Max	2, 3	0, 4	0, 4	0, 4	
C2D1 CFB					
n	3	10	60	106	
LS Mean (StdErr) [2]	-0.75 (0.595)	-0.61 (0.526)	-0.00 (0.172)	-0.14 (0.137)	
95% CI [2]	-2.10, 0.60	-1.80, 0.58	-0.34, 0.34	-0.41, 0.13	
Difference (95% CI) in CFB [2]		0.14 (-1.40, 1.68)		-0.14 (-0.51, 0.24)	
p-value [3]		0.838		0.471	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-thpy-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	10	60	99	
Mean (StdDev)	2.7 (0.58)	1.8 (1.40)	2.0 (1.41)	1.4 (1.42)	
Median	3.0	2.5	2.0	1.0	
Min, Max	2, 3	0, 3	0, 4	0, 4	
C3D1 CFB					
n	3	10	58	99	
LS Mean (StdErr) [2]	-0.32 (0.837)	-0.91 (0.741)	-0.08 (0.190)	-0.31 (0.150)	
95% CI [2]	-2.22, 1.57	-2.59, 0.76	-0.45, 0.30	-0.61, -0.02	
Difference (95% CI) in CFB [2]		-0.59 (-2.76, 1.57)		-0.23 (-0.65, 0.18)	
p-value [3]		0.552		0.265	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-thpy-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	2	9	54	104	
Mean (StdDev)	3.0 (0.00)	1.8 (1.48)	1.8 (1.28)	1.5 (1.43)	
Median	3.0	2.0	2.0	1.0	
Min, Max	3, 3	0, 4	0, 4	0, 4	
C4D1 CFB					
n	2	9	52	102	
LS Mean (StdErr) [2]	-0.16 (1.126)	-0.95 (0.752)	-0.23 (0.182)	-0.19 (0.142)	
95% CI [2]	-2.82, 2.51	-2.73, 0.83	-0.59, 0.13	-0.47, 0.09	
Difference (95% CI) in CFB [2]		-0.79 (-3.59, 2.02)		0.04 (-0.35, 0.43)	
p-value [3]		0.527		0.824	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	8	57	101	
Mean (StdDev)	2.7 (0.58)	1.6 (1.51)	1.8 (1.37)	1.4 (1.40)	
Median	3.0	2.0	2.0	1.0	
Min, Max	2, 3	0, 4	0, 4	0, 4	
C5D1 CFB					
n	3	8	56	97	
LS Mean (StdErr) [2]	-0.29 (0.789)	-0.79 (0.696)	-0.22 (0.201)	-0.29 (0.159)	
95% CI [2]	-2.16, 1.57	-2.44, 0.85	-0.62, 0.17	-0.60, 0.03	
Difference (95% CI) in CFB [2]		-0.50 (-2.64, 1.64)		-0.07 (-0.50, 0.37)	
p-value [3]		0.598		0.768	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	55	102	
Mean (StdDev)	2.7 (0.58)	1.8 (1.64)	1.9 (1.48)	1.4 (1.34)	
Median	3.0	2.0	2.0	1.0	
Min, Max	2, 3	0, 4	0, 4	0, 4	
C6D1 CFB					
n	3	9	54	98	
LS Mean (StdErr) [2]	-0.48 (1.009)	-1.09 (0.892)	-0.26 (0.205)	-0.38 (0.161)	
95% CI [2]	-2.80, 1.85	-3.14, 0.97	-0.66, 0.15	-0.70, -0.07	
Difference (95% CI) in CFB [2]		-0.61 (-3.28, 2.05)		-0.13 (-0.57, 0.32)	
p-value [3]		0.611		0.575	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	8	55	103	
Mean (StdDev)	2.7 (1.15)	1.0 (1.41)	1.9 (1.51)	1.3 (1.35)	
Median	2.0	0.5	2.0	1.0	
Min, Max	2, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	3	8	54	99	
LS Mean (StdErr) [2]	-0.32 (1.154)	-1.49 (1.019)	0.03 (0.201)	-0.25 (0.155)	
95% CI [2]	-3.05, 2.41	-3.89, 0.92	-0.37, 0.43	-0.55, 0.06	
Difference (95% CI) in CFB [2]		-1.17 (-4.30, 1.97)		-0.28 (-0.71, 0.15)	
Hedges'G (95% CI) in CFB		-0.39 (-2.05, 1.04)		-0.18 (-0.52, 0.15)	
p-value [3]		0.408		0.203	
					0.418

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	62	109	
Mean (StdDev)	2.3 (1.53)	1.9 (1.10)	1.7 (1.23)	1.8 (1.34)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	62	109	
Mean (StdDev)	1.3 (0.58)	1.7 (1.25)	1.5 (1.11)	1.3 (1.26)	
Median	1.0	1.0	1.0	1.0	
Min, Max	1, 2	0, 4	0, 4	0, 4	
C2D1 CFB					
n	3	10	60	106	
LS Mean (StdErr) [2]	-1.07 (0.438)	-0.23 (0.388)	-0.24 (0.124)	-0.44 (0.099)	
95% CI [2]	-2.06, -0.08	-1.11, 0.64	-0.48, 0.01	-0.63, -0.24	
Difference (95% CI) in CFB [2]		0.84 (-0.30, 1.97)		-0.20 (-0.47, 0.07)	
p-value [3]		0.129		0.151	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	10	60	99	
Mean (StdDev)	1.3 (1.53)	1.3 (1.06)	1.6 (1.16)	1.1 (1.23)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C3D1 CFB					
n	3	10	58	99	
LS Mean (StdErr) [2]	-1.18 (0.635)	-0.87 (0.562)	-0.20 (0.166)	-0.66 (0.131)	
95% CI [2]	-2.62, 0.26	-2.14, 0.40	-0.53, 0.13	-0.92, -0.40	
Difference (95% CI) in CFB [2]		0.31 (-1.34, 1.95)		-0.46 (-0.82, -0.10)	
p-value [3]		0.683		0.014	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	2	9	54	104	
Mean (StdDev)	1.5 (0.71)	1.2 (0.83)	1.6 (1.17)	1.1 (1.22)	
Median	1.5	1.0	1.5	1.0	
Min, Max	1, 2	0, 2	0, 4	0, 4	
C4D1 CFB					
n	2	9	52	102	
LS Mean (StdErr) [2]	-0.34 (0.360)	-0.55 (0.241)	-0.25 (0.180)	-0.74 (0.140)	
95% CI [2]	-1.19, 0.51	-1.12, 0.02	-0.60, 0.11	-1.02, -0.46	
Difference (95% CI) in CFB [2]		-0.21 (-1.11, 0.69)		-0.50 (-0.88, -0.11)	
p-value [3]		0.596		0.012	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	8	57	101	
Mean (StdDev)	1.3 (0.58)	0.8 (0.71)	1.5 (1.17)	1.1 (1.25)	
Median	1.0	1.0	1.0	1.0	
Min, Max	1, 2	0, 2	0, 4	0, 4	
C5D1 CFB					
n	3	8	56	97	
LS Mean (StdErr) [2]	-1.10 (0.534)	-0.93 (0.472)	-0.30 (0.163)	-0.78 (0.129)	
95% CI [2]	-2.36, 0.17	-2.05, 0.18	-0.62, 0.02	-1.03, -0.52	
Difference (95% CI) in CFB [2]		0.17 (-1.29, 1.62)		-0.48 (-0.83, -0.12)	
p-value [3]		0.794		0.009	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-thpy-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	55	102	
Mean (StdDev)	1.7 (0.58)	0.9 (0.78)	1.5 (1.20)	1.1 (1.23)	
Median	2.0	1.0	1.0	1.0	
Min, Max	1, 2	0, 2	0, 4	0, 4	
C6D1 CFB					
n	3	9	54	98	
LS Mean (StdErr) [2]	-0.65 (0.536)	-0.68 (0.473)	-0.26 (0.165)	-0.71 (0.130)	
95% CI [2]	-1.89, 0.58	-1.77, 0.42	-0.59, 0.07	-0.96, -0.45	
Difference (95% CI) in CFB [2]		-0.02 (-1.44, 1.39)		-0.45 (-0.81, -0.09)	
p-value [3]		0.970		0.016	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-thpy-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	8	55	103	
Mean (StdDev)	1.7 (1.15)	0.5 (0.53)	1.3 (1.12)	1.1 (1.19)	
Median	1.0	0.5	1.0	1.0	
Min, Max	1, 3	0, 1	0, 4	0, 4	
C7D1 CFB					
n	3	8	54	99	
LS Mean (StdErr) [2]	-0.76 (0.677)	-1.17 (0.598)	-0.34 (0.159)	-0.60 (0.123)	
95% CI [2]	-2.36, 0.84	-2.59, 0.24	-0.65, -0.02	-0.85, -0.36	
Difference (95% CI) in CFB [2]		-0.42 (-2.26, 1.42)		-0.27 (-0.61, 0.07)	
Hedges'G (95% CI) in CFB		-0.24 (-1.85, 1.23)		-0.22 (-0.56, 0.11)	
p-value [3]		0.609		0.125	
					0.821

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-thpy-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	62	109	
Mean (StdDev)	1.7 (0.58)	1.9 (1.29)	1.2 (1.30)	1.4 (1.49)	
Median	2.0	2.0	1.0	1.0	
Min, Max	1, 2	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-thpy-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	62	109	
Mean (StdDev)	1.3 (1.15)	1.0 (1.25)	1.2 (1.36)	1.3 (1.38)	
Median	2.0	1.0	1.0	1.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	
C2D1 CFB					
n	3	10	60	106	
LS Mean (StdErr) [2]	0.04 (0.598)	-0.17 (0.529)	0.02 (0.144)	-0.08 (0.115)	
95% CI [2]	-1.32, 1.39	-1.36, 1.03	-0.27, 0.30	-0.31, 0.15	
Difference (95% CI) in CFB [2]		-0.20 (-1.75, 1.34)		-0.10 (-0.41, 0.21)	
p-value [3]		0.772		0.530	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-thpy-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	10	60	99	
Mean (StdDev)	1.0 (1.00)	0.8 (1.23)	1.1 (1.21)	1.0 (1.25)	
Median	1.0	0.5	1.0	0.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	
C3D1 CFB					
n	3	10	58	99	
LS Mean (StdErr) [2]	-0.46 (0.598)	-0.67 (0.529)	-0.07 (0.169)	-0.28 (0.133)	
95% CI [2]	-1.82, 0.89	-1.86, 0.53	-0.41, 0.26	-0.55, -0.02	
Difference (95% CI) in CFB [2]		-0.20 (-1.75, 1.34)		-0.21 (-0.58, 0.16)	
p-value [3]		0.772		0.260	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-thpy-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	2	9	54	104	
Mean (StdDev)	1.5 (0.71)	0.2 (0.44)	1.4 (1.29)	1.1 (1.26)	
Median	1.5	0.0	1.0	1.0	
Min, Max	1, 2	0, 1	0, 4	0, 4	
C4D1 CFB					
n	2	9	52	102	
LS Mean (StdErr) [2]	0.37 (0.748)	-0.79 (0.499)	-0.04 (0.176)	-0.42 (0.137)	
95% CI [2]	-1.40, 2.14	-1.97, 0.39	-0.38, 0.31	-0.69, -0.15	
Difference (95% CI) in CFB [2]		-1.16 (-3.02, 0.70)		-0.38 (-0.76, -0.01)	
p-value [3]		0.185		0.046	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-thpy-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	8	57	101	
Mean (StdDev)	2.0 (1.00)	0.3 (0.46)	1.2 (1.26)	1.0 (1.26)	
Median	2.0	0.0	1.0	0.0	
Min, Max	1, 3	0, 1	0, 4	0, 4	
C5D1 CFB					
n	3	8	56	97	
LS Mean (StdErr) [2]	0.61 (0.590)	-0.72 (0.521)	-0.10 (0.162)	-0.51 (0.129)	
95% CI [2]	-0.78, 2.01	-1.95, 0.51	-0.42, 0.22	-0.77, -0.26	
Difference (95% CI) in CFB [2]		-1.33 (-2.94, 0.27)		-0.41 (-0.77, -0.06)	
p-value [3]		0.090		0.023	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	55	102	
Mean (StdDev)	1.0 (1.00)	0.2 (0.44)	1.2 (1.26)	1.0 (1.23)	
Median	1.0	0.0	1.0	0.5	
Min, Max	0, 2	0, 1	0, 4	0, 4	
C6D1 CFB					
n	3	9	54	98	
LS Mean (StdErr) [2]	-0.33 (0.622)	-0.76 (0.549)	-0.05 (0.168)	-0.49 (0.132)	
95% CI [2]	-1.76, 1.10	-2.03, 0.50	-0.38, 0.29	-0.75, -0.23	
Difference (95% CI) in CFB [2]		-0.44 (-2.08, 1.21)		-0.45 (-0.81, -0.08)	
p-value [3]		0.558		0.017	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-thpy-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	8	55	103	
Mean (StdDev)	1.0 (1.00)	0.0 (0.00)	1.2 (1.21)	1.0 (1.27)	
Median	1.0	0.0	1.0	0.0	
Min, Max	0, 2	0, 0	0, 4	0, 4	
C7D1 CFB					
n	3	8	54	99	
LS Mean (StdErr) [2]	-0.36 (0.676)	-1.03 (0.597)	0.01 (0.163)	-0.34 (0.126)	
95% CI [2]	-1.96, 1.24	-2.44, 0.38	-0.31, 0.34	-0.59, -0.09	
Difference (95% CI) in CFB [2]		-0.67 (-2.50, 1.17)		-0.36 (-0.71, -0.01)	
Hedges'G (95% CI) in CFB		-0.38 (-2.04, 1.05)		-0.29 (-0.63, 0.04)	
p-value [3]		0.419		0.045	
					0.469

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	62	109	
Mean (StdDev)	2.7 (0.58)	2.5 (1.35)	2.0 (1.13)	1.9 (1.28)	
Median	3.0	2.5	2.0	2.0	
Min, Max	2, 3	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-thpy-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	62	109	
Mean (StdDev)	2.0 (1.00)	1.6 (1.43)	1.5 (1.26)	1.4 (1.25)	
Median	2.0	1.5	1.5	1.0	
Min, Max	1, 3	0, 4	0, 4	0, 4	
C2D1 CFB					
n	3	10	60	106	
LS Mean (StdErr) [2]	-0.54 (0.982)	-0.62 (0.869)	-0.51 (0.148)	-0.58 (0.118)	
95% CI [2]	-2.76, 1.69	-2.58, 1.35	-0.80, -0.22	-0.81, -0.34	
Difference (95% CI) in CFB [2]		-0.08 (-2.62, 2.46)		-0.07 (-0.39, 0.25)	
p-value [3]		0.944		0.671	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-thpy-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	10	60	99	
Mean (StdDev)	2.3 (0.58)	1.6 (1.07)	1.5 (1.13)	1.3 (1.14)	
Median	2.0	2.0	2.0	1.0	
Min, Max	2, 3	0, 3	0, 4	0, 4	
C3D1 CFB					
n	3	10	58	99	
LS Mean (StdErr) [2]	-0.00 (0.866)	-0.14 (0.766)	-0.44 (0.147)	-0.62 (0.116)	
95% CI [2]	-1.96, 1.96	-1.88, 1.59	-0.73, -0.15	-0.85, -0.39	
Difference (95% CI) in CFB [2]		-0.14 (-2.38, 2.10)		-0.18 (-0.50, 0.14)	
p-value [3]		0.888		0.269	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	2	9	54	104	
Mean (StdDev)	2.0 (1.41)	1.1 (1.05)	1.5 (1.25)	1.4 (1.24)	
Median	2.0	1.0	1.0	1.0	
Min, Max	1, 3	0, 3	0, 4	0, 4	
C4D1 CFB					
n	2	9	52	102	
LS Mean (StdErr) [2]	-0.91 (0.968)	-0.70 (0.646)	-0.35 (0.175)	-0.63 (0.136)	
95% CI [2]	-3.20, 1.38	-2.23, 0.83	-0.69, -0.00	-0.90, -0.36	
Difference (95% CI) in CFB [2]		0.21 (-2.20, 2.62)		-0.28 (-0.66, 0.09)	
p-value [3]		0.842		0.138	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	8	57	101	
Mean (StdDev)	2.0 (0.00)	0.6 (0.92)	1.4 (1.34)	1.2 (1.20)	
Median	2.0	0.0	1.0	1.0	
Min, Max	2, 2	0, 2	0, 4	0, 4	
C5D1 CFB					
n	3	8	56	97	
LS Mean (StdErr) [2]	-0.31 (0.712)	-1.06 (0.629)	-0.39 (0.166)	-0.76 (0.132)	
95% CI [2]	-2.00, 1.37	-2.55, 0.42	-0.72, -0.07	-1.02, -0.50	
Difference (95% CI) in CFB [2]		-0.75 (-2.69, 1.19)		-0.36 (-0.72, 0.00)	
p-value [3]		0.390		0.050	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	55	102	
Mean (StdDev)	2.0 (1.00)	0.4 (0.73)	1.6 (1.30)	1.1 (1.14)	
Median	2.0	0.0	1.0	1.0	
Min, Max	1, 3	0, 2	0, 4	0, 4	
C6D1 CFB					
n	3	9	54	98	
LS Mean (StdErr) [2]	-0.45 (0.982)	-1.68 (0.868)	-0.34 (0.169)	-1.00 (0.132)	
95% CI [2]	-2.72, 1.81	-3.68, 0.33	-0.67, -0.00	-1.27, -0.74	
Difference (95% CI) in CFB [2]		-1.22 (-3.82, 1.37)		-0.67 (-1.04, -0.30)	
p-value [3]		0.308		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	8	55	103	
Mean (StdDev)	1.7 (0.58)	0.4 (0.52)	1.6 (1.38)	1.2 (1.27)	
Median	2.0	0.0	2.0	1.0	
Min, Max	1, 2	0, 1	0, 4	0, 4	
C7D1 CFB					
n	3	8	54	99	
LS Mean (StdErr) [2]	-0.68 (0.826)	-1.51 (0.729)	-0.25 (0.194)	-0.68 (0.150)	
95% CI [2]	-2.63, 1.27	-3.24, 0.21	-0.63, 0.14	-0.97, -0.38	
Difference (95% CI) in CFB [2]		-0.83 (-3.08, 1.41)		-0.43 (-0.85, -0.02)	
Hedges'G (95% CI) in CFB		-0.39 (-2.05, 1.04)		-0.29 (-0.63, 0.04)	
p-value [3]		0.409		0.042	
					0.459

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	62	109	
Mean (StdDev)	2.7 (0.58)	2.6 (1.17)	2.3 (1.02)	2.3 (1.20)	
Median	3.0	2.5	2.0	2.0	
Min, Max	2, 3	1, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	62	109	
Mean (StdDev)	1.3 (0.58)	1.6 (1.17)	1.8 (1.15)	1.7 (1.31)	
Median	1.0	1.0	2.0	2.0	
Min, Max	1, 2	0, 4	0, 4	0, 4	
C2D1 CFB					
n	3	10	60	106	
LS Mean (StdErr) [2]	-1.50 (0.707)	-1.36 (0.625)	-0.41 (0.151)	-0.55 (0.120)	
95% CI [2]	-3.10, 0.10	-2.77, 0.06	-0.70, -0.11	-0.79, -0.32	
Difference (95% CI) in CFB [2]		0.14 (-1.69, 1.97)		-0.15 (-0.48, 0.18)	
p-value [3]		0.864		0.377	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	10	60	99	
Mean (StdDev)	2.3 (1.15)	1.5 (1.18)	1.8 (1.12)	1.4 (1.13)	
Median	3.0	1.5	2.0	1.0	
Min, Max	1, 3	0, 4	0, 4	0, 4	
C3D1 CFB					
n	3	10	58	99	
LS Mean (StdErr) [2]	-0.29 (0.953)	-0.94 (0.843)	-0.44 (0.159)	-0.82 (0.125)	
95% CI [2]	-2.44, 1.87	-2.85, 0.97	-0.75, -0.12	-1.06, -0.57	
Difference (95% CI) in CFB [2]		-0.65 (-3.12, 1.81)		-0.38 (-0.72, -0.03)	
p-value [3]		0.564		0.033	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	2	9	54	103	
Mean (StdDev)	2.0 (0.00)	0.9 (0.78)	1.8 (1.15)	1.5 (1.28)	
Median	2.0	1.0	2.0	2.0	
Min, Max	2, 2	0, 2	0, 4	0, 4	
C4D1 CFB					
n	2	9	52	101	
LS Mean (StdErr) [2]	-1.21 (0.984)	-1.26 (0.657)	-0.55 (0.175)	-0.91 (0.136)	
95% CI [2]	-3.54, 1.12	-2.82, 0.29	-0.90, -0.21	-1.18, -0.64	
Difference (95% CI) in CFB [2]		-0.05 (-2.50, 2.40)		-0.36 (-0.73, 0.02)	
p-value [3]		0.961		0.061	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	8	57	101	
Mean (StdDev)	2.3 (1.15)	1.1 (0.99)	1.6 (1.33)	1.4 (1.25)	
Median	3.0	1.0	2.0	1.0	
Min, Max	1, 3	0, 3	0, 4	0, 4	
C5D1 CFB					
n	3	8	56	97	
LS Mean (StdErr) [2]	-0.35 (0.627)	-1.18 (0.554)	-0.65 (0.184)	-0.97 (0.146)	
95% CI [2]	-1.83, 1.14	-2.49, 0.13	-1.02, -0.29	-1.25, -0.68	
Difference (95% CI) in CFB [2]		-0.83 (-2.54, 0.87)		-0.31 (-0.71, 0.09)	
p-value [3]		0.286		0.123	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	55	102	
Mean (StdDev)	1.7 (1.53)	1.1 (1.27)	1.7 (1.24)	1.4 (1.26)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C6D1 CFB					
n	3	9	54	98	
LS Mean (StdErr) [2]	-0.95 (0.767)	-1.18 (0.678)	-0.52 (0.185)	-1.03 (0.145)	
95% CI [2]	-2.72, 0.82	-2.74, 0.39	-0.88, -0.15	-1.31, -0.74	
Difference (95% CI) in CFB [2]		-0.22 (-2.25, 1.80)		-0.51 (-0.92, -0.11)	
p-value [3]		0.806		0.013	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	8	55	103	
Mean (StdDev)	2.7 (0.58)	0.6 (0.52)	1.5 (1.23)	1.4 (1.28)	
Median	3.0	1.0	1.0	1.0	
Min, Max	2, 3	0, 1	0, 4	0, 4	
C7D1 CFB					
n	3	8	54	99	
LS Mean (StdErr) [2]	0.15 (0.534)	-1.68 (0.472)	-0.62 (0.188)	-0.78 (0.145)	
95% CI [2]	-1.11, 1.42	-2.80, -0.57	-0.99, -0.25	-1.06, -0.49	
Difference (95% CI) in CFB [2]		-1.83 (-3.29, -0.38)		-0.15 (-0.55, 0.25)	
Hedges'G (95% CI) in CFB		-1.34 (-3.42, -0.01)		-0.11 (-0.44, 0.23)	
p-value [3]		0.020		0.456	
					0.034

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	62	109	
Mean (StdDev)	2.3 (0.58)	3.0 (0.94)	2.6 (1.16)	2.7 (1.10)	
Median	2.0	3.0	3.0	3.0	
Min, Max	2, 3	1, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	62	109	
Mean (StdDev)	2.0 (1.00)	2.5 (1.18)	2.3 (1.14)	2.2 (1.20)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 3	1, 4	0, 4	0, 4	
C2D1 CFB					
n	3	10	60	106	
LS Mean (StdErr) [2]	-0.57 (0.700)	-1.02 (0.619)	-0.31 (0.139)	-0.54 (0.111)	
95% CI [2]	-2.15, 1.01	-2.42, 0.38	-0.58, -0.03	-0.76, -0.32	
Difference (95% CI) in CFB [2]		-0.45 (-2.26, 1.36)		-0.23 (-0.53, 0.07)	
p-value [3]		0.588		0.133	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	10	60	100	
Mean (StdDev)	2.7 (1.15)	2.5 (1.08)	2.2 (1.18)	2.1 (1.15)	
Median	2.0	2.5	2.0	2.0	
Min, Max	2, 4	1, 4	0, 4	0, 4	
C3D1 CFB					
n	3	10	58	99	
LS Mean (StdErr) [2]	0.54 (0.699)	-0.10 (0.618)	-0.53 (0.148)	-0.67 (0.117)	
95% CI [2]	-1.05, 2.12	-1.50, 1.30	-0.82, -0.24	-0.90, -0.44	
Difference (95% CI) in CFB [2]		-0.63 (-2.44, 1.17)		-0.14 (-0.46, 0.18)	
p-value [3]		0.449		0.388	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	2	9	54	104	
Mean (StdDev)	2.0 (0.00)	2.3 (0.87)	2.4 (1.16)	2.0 (1.19)	
Median	2.0	2.0	2.0	2.0	
Min, Max	2, 2	1, 4	0, 4	0, 4	
C4D1 CFB					
n	2	9	52	102	
LS Mean (StdErr) [2]	-0.79 (1.077)	-0.74 (0.719)	-0.26 (0.173)	-0.69 (0.135)	
95% CI [2]	-3.34, 1.76	-2.44, 0.96	-0.60, 0.08	-0.96, -0.42	
Difference (95% CI) in CFB [2]		0.05 (-2.63, 2.73)		-0.43 (-0.80, -0.06)	
p-value [3]		0.964		0.023	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	8	57	101	
Mean (StdDev)	2.0 (0.00)	2.0 (1.20)	2.3 (1.15)	2.1 (1.14)	
Median	2.0	2.0	2.0	2.0	
Min, Max	2, 2	0, 4	0, 4	0, 4	
C5D1 CFB					
n	3	8	56	97	
LS Mean (StdErr) [2]	-0.09 (0.843)	-0.51 (0.745)	-0.38 (0.178)	-0.72 (0.141)	
95% CI [2]	-2.08, 1.90	-2.27, 1.25	-0.73, -0.03	-0.99, -0.44	
Difference (95% CI) in CFB [2]		-0.42 (-2.71, 1.88)		-0.34 (-0.72, 0.05)	
p-value [3]		0.680		0.088	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	55	102	
Mean (StdDev)	2.3 (0.58)	1.9 (1.17)	2.3 (1.27)	1.8 (1.15)	
Median	2.0	2.0	2.0	2.0	
Min, Max	2, 3	0, 4	0, 4	0, 4	
C6D1 CFB					
n	3	9	54	98	
LS Mean (StdErr) [2]	0.04 (0.898)	-0.88 (0.794)	-0.29 (0.181)	-0.86 (0.142)	
95% CI [2]	-2.04, 2.11	-2.71, 0.95	-0.65, 0.07	-1.14, -0.58	
Difference (95% CI) in CFB [2]		-0.92 (-3.29, 1.46)		-0.57 (-0.96, -0.17)	
p-value [3]		0.399		0.005	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	8	55	103	
Mean (StdDev)	2.0 (1.00)	1.3 (0.89)	2.3 (1.25)	1.9 (1.17)	
Median	2.0	1.5	2.0	2.0	
Min, Max	1, 3	0, 2	0, 4	0, 4	
C7D1 CFB					
n	3	8	54	99	
LS Mean (StdErr) [2]	-0.32 (0.948)	-1.49 (0.837)	-0.22 (0.174)	-0.74 (0.134)	
95% CI [2]	-2.56, 1.92	-3.47, 0.49	-0.56, 0.13	-1.00, -0.47	
Difference (95% CI) in CFB [2]		-1.17 (-3.74, 1.41)		-0.52 (-0.89, -0.14)	
Hedges'G (95% CI) in CFB		-0.48 (-2.17, 0.94)		-0.39 (-0.73, -0.06)	
p-value [3]		0.320		0.007	
					0.449

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	62	109	
Mean (StdDev)	2.3 (0.58)	2.3 (1.49)	2.2 (1.37)	2.0 (1.30)	
Median	2.0	3.0	2.5	2.0	
Min, Max	2, 3	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	62	109	
Mean (StdDev)	2.3 (0.58)	1.7 (1.42)	1.9 (1.31)	1.7 (1.32)	
Median	2.0	2.0	2.0	2.0	
Min, Max	2, 3	0, 4	0, 4	0, 4	
C2D1 CFB					
n	3	10	60	106	
LS Mean (StdErr) [2]	-0.07 (0.609)	-0.81 (0.539)	-0.26 (0.142)	-0.31 (0.114)	
95% CI [2]	-1.45, 1.31	-2.02, 0.41	-0.54, 0.03	-0.54, -0.09	
Difference (95% CI) in CFB [2]		-0.73 (-2.31, 0.84)		-0.06 (-0.37, 0.25)	
p-value [3]		0.319		0.722	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	10	59	100	
Mean (StdDev)	2.0 (1.00)	1.6 (1.26)	1.7 (1.28)	1.5 (1.23)	
Median	2.0	2.0	2.0	1.0	
Min, Max	1, 3	0, 4	0, 4	0, 4	
C3D1 CFB					
n	3	10	57	99	
LS Mean (StdErr) [2]	-0.50 (0.957)	-1.07 (0.847)	-0.45 (0.150)	-0.48 (0.118)	
95% CI [2]	-2.67, 1.67	-2.99, 0.84	-0.75, -0.15	-0.71, -0.24	
Difference (95% CI) in CFB [2]		-0.57 (-3.05, 1.90)		-0.03 (-0.35, 0.30)	
p-value [3]		0.614		0.874	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	2	9	54	104	
Mean (StdDev)	2.0 (0.00)	1.4 (1.24)	1.8 (1.38)	1.6 (1.33)	
Median	2.0	2.0	2.0	1.0	
Min, Max	2, 2	0, 3	0, 4	0, 4	
C4D1 CFB					
n	2	9	52	102	
LS Mean (StdErr) [2]	-0.43 (1.231)	-0.86 (0.822)	-0.47 (0.176)	-0.54 (0.137)	
95% CI [2]	-3.35, 2.48	-2.80, 1.09	-0.82, -0.12	-0.81, -0.27	
Difference (95% CI) in CFB [2]		-0.42 (-3.49, 2.65)		-0.07 (-0.45, 0.31)	
p-value [3]		0.755		0.709	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-thpy-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	8	57	101	
Mean (StdDev)	2.3 (1.15)	0.9 (0.99)	1.7 (1.35)	1.4 (1.27)	
Median	3.0	0.5	2.0	1.0	
Min, Max	1, 3	0, 2	0, 4	0, 4	
C5D1 CFB					
n	3	8	56	97	
LS Mean (StdErr) [2]	-0.07 (0.889)	-1.24 (0.785)	-0.54 (0.182)	-0.70 (0.144)	
95% CI [2]	-2.17, 2.03	-3.09, 0.62	-0.90, -0.18	-0.99, -0.42	
Difference (95% CI) in CFB [2]		-1.17 (-3.58, 1.25)		-0.17 (-0.56, 0.23)	
p-value [3]		0.291		0.412	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	55	102	
Mean (StdDev)	2.7 (0.58)	1.2 (1.09)	1.9 (1.43)	1.3 (1.22)	
Median	3.0	1.0	2.0	1.0	
Min, Max	2, 3	0, 3	0, 4	0, 4	
C6D1 CFB					
n	3	9	54	98	
LS Mean (StdErr) [2]	0.43 (0.637)	-0.74 (0.563)	-0.32 (0.187)	-0.76 (0.146)	
95% CI [2]	-1.04, 1.90	-2.03, 0.56	-0.69, 0.05	-1.05, -0.47	
Difference (95% CI) in CFB [2]		-1.16 (-2.85, 0.52)		-0.44 (-0.85, -0.03)	
p-value [3]		0.149		0.034	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	8	55	103	
Mean (StdDev)	2.3 (0.58)	0.9 (0.99)	1.8 (1.39)	1.3 (1.33)	
Median	2.0	0.5	2.0	1.0	
Min, Max	2, 3	0, 2	0, 4	0, 4	
C7D1 CFB					
n	3	8	54	99	
LS Mean (StdErr) [2]	0.06 (0.818)	-1.19 (0.722)	-0.36 (0.171)	-0.64 (0.132)	
95% CI [2]	-1.87, 2.00	-2.90, 0.52	-0.70, -0.02	-0.90, -0.38	
Difference (95% CI) in CFB [2]		-1.25 (-3.47, 0.97)		-0.28 (-0.65, 0.09)	
Hedges'G (95% CI) in CFB		-0.59 (-2.33, 0.80)		-0.21 (-0.55, 0.12)	
p-value [3]		0.225		0.134	
					0.245

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	62	109	
Mean (StdDev)	2.3 (0.58)	2.8 (1.23)	2.4 (1.03)	2.5 (1.06)	
Median	2.0	3.0	2.0	2.0	
Min, Max	2, 3	1, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	62	109	
Mean (StdDev)	1.7 (0.58)	2.0 (1.33)	2.0 (1.08)	1.8 (1.12)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 2	0, 4	0, 4	0, 4	
C2D1 CFB					
n	3	10	60	106	
LS Mean (StdErr) [2]	-0.82 (0.635)	-1.13 (0.562)	-0.43 (0.158)	-0.69 (0.126)	
95% CI [2]	-2.26, 0.62	-2.40, 0.14	-0.74, -0.11	-0.94, -0.44	
Difference (95% CI) in CFB [2]		-0.31 (-1.95, 1.34)		-0.26 (-0.61, 0.08)	
p-value [3]		0.683		0.131	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	10	60	99	
Mean (StdDev)	2.7 (0.58)	1.6 (1.17)	2.0 (1.13)	1.7 (1.06)	
Median	3.0	1.0	2.0	2.0	
Min, Max	2, 3	0, 4	0, 4	0, 4	
C3D1 CFB					
n	3	10	58	98	
LS Mean (StdErr) [2]	0.21 (0.908)	-1.44 (0.803)	-0.50 (0.166)	-0.80 (0.131)	
95% CI [2]	-1.84, 2.27	-3.26, 0.38	-0.82, -0.17	-1.06, -0.54	
Difference (95% CI) in CFB [2]		-1.65 (-4.00, 0.69)		-0.30 (-0.66, 0.06)	
p-value [3]		0.146		0.105	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	2	9	54	104	
Mean (StdDev)	2.5 (0.71)	1.3 (1.12)	1.9 (1.13)	1.7 (1.15)	
Median	2.5	1.0	2.0	2.0	
Min, Max	2, 3	0, 3	0, 4	0, 4	
C4D1 CFB					
n	2	9	52	102	
LS Mean (StdErr) [2]	-0.14 (1.134)	-1.62 (0.757)	-0.60 (0.176)	-0.87 (0.137)	
95% CI [2]	-2.83, 2.54	-3.41, 0.17	-0.95, -0.25	-1.14, -0.60	
Difference (95% CI) in CFB [2]		-1.47 (-4.30, 1.35)		-0.27 (-0.65, 0.10)	
p-value [3]		0.257		0.151	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	8	57	101	
Mean (StdDev)	2.0 (1.00)	1.0 (0.76)	1.8 (1.18)	1.6 (1.16)	
Median	2.0	1.0	2.0	2.0	
Min, Max	1, 3	0, 2	0, 4	0, 4	
C5D1 CFB					
n	3	8	56	97	
LS Mean (StdErr) [2]	-0.40 (1.021)	-1.57 (0.902)	-0.64 (0.183)	-1.02 (0.145)	
95% CI [2]	-2.82, 2.01	-3.70, 0.56	-1.00, -0.28	-1.31, -0.74	
Difference (95% CI) in CFB [2]		-1.17 (-3.94, 1.61)		-0.38 (-0.78, 0.01)	
p-value [3]		0.353		0.059	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	55	102	
Mean (StdDev)	2.3 (0.58)	1.2 (0.83)	1.9 (1.17)	1.5 (1.18)	
Median	2.0	1.0	2.0	2.0	
Min, Max	2, 3	0, 3	0, 4	0, 4	
C6D1 CFB					
n	3	9	54	98	
LS Mean (StdErr) [2]	-0.06 (0.674)	-1.53 (0.596)	-0.55 (0.183)	-1.09 (0.144)	
95% CI [2]	-1.61, 1.49	-2.90, -0.16	-0.91, -0.19	-1.37, -0.81	
Difference (95% CI) in CFB [2]		-1.47 (-3.25, 0.31)		-0.54 (-0.94, -0.14)	
p-value [3]		0.093		0.009	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	8	55	103	
Mean (StdDev)	2.3 (0.58)	0.6 (0.74)	1.9 (1.30)	1.6 (1.29)	
Median	2.0	0.5	2.0	2.0	
Min, Max	2, 3	0, 2	0, 4	0, 4	
C7D1 CFB					
n	3	8	54	99	
LS Mean (StdErr) [2]	-0.02 (0.912)	-2.27 (0.805)	-0.47 (0.203)	-0.91 (0.157)	
95% CI [2]	-2.18, 2.14	-4.17, -0.37	-0.87, -0.07	-1.22, -0.60	
Difference (95% CI) in CFB [2]		-2.25 (-4.73, 0.23)		-0.44 (-0.87, -0.00)	
Hedges'G (95% CI) in CFB		-0.96 (-2.86, 0.39)		-0.28 (-0.62, 0.05)	
p-value [3]		0.069		0.048	
					0.048

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	61	109	
Mean (StdDev)	2.0 (1.00)	2.6 (1.07)	2.1 (1.27)	2.2 (1.19)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 3	1, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
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Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	62	109	
Mean (StdDev)	2.0 (1.00)	1.8 (1.14)	1.9 (1.25)	1.8 (1.19)	
Median	2.0	1.0	2.0	2.0	
Min, Max	1, 3	1, 4	0, 4	0, 4	
C2D1 CFB					
n	3	10	59	106	
LS Mean (StdErr) [2]	0.07 (0.741)	-0.62 (0.656)	-0.16 (0.152)	-0.41 (0.121)	
95% CI [2]	-1.61, 1.75	-2.11, 0.86	-0.46, 0.14	-0.65, -0.17	
Difference (95% CI) in CFB [2]		-0.69 (-2.61, 1.22)		-0.26 (-0.59, 0.07)	
p-value [3]		0.434		0.128	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-thpy-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	10	60	100	
Mean (StdDev)	2.0 (1.00)	1.7 (1.16)	1.8 (1.21)	1.6 (1.10)	
Median	2.0	1.5	2.0	2.0	
Min, Max	1, 3	0, 4	0, 4	0, 4	
C3D1 CFB					
n	3	10	57	99	
LS Mean (StdErr) [2]	0.11 (0.826)	-0.65 (0.731)	-0.18 (0.149)	-0.57 (0.117)	
95% CI [2]	-1.76, 1.98	-2.30, 1.00	-0.48, 0.11	-0.80, -0.34	
Difference (95% CI) in CFB [2]		-0.76 (-2.89, 1.38)		-0.39 (-0.71, -0.06)	
p-value [3]		0.444		0.020	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-thpy-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	2	9	54	104	
Mean (StdDev)	2.5 (0.71)	1.8 (1.09)	1.8 (1.25)	1.6 (1.26)	
Median	2.5	2.0	2.0	1.0	
Min, Max	2, 3	0, 3	0, 4	0, 4	
C4D1 CFB					
n	2	9	51	102	
LS Mean (StdErr) [2]	-0.18 (1.428)	-0.61 (0.953)	-0.22 (0.175)	-0.62 (0.136)	
95% CI [2]	-3.56, 3.19	-2.86, 1.65	-0.56, 0.13	-0.89, -0.35	
Difference (95% CI) in CFB [2]		-0.42 (-3.98, 3.13)		-0.40 (-0.78, -0.03)	
p-value [3]		0.788		0.035	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-thpy-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	8	57	101	
Mean (StdDev)	2.0 (1.00)	1.3 (1.04)	1.7 (1.12)	1.5 (1.16)	
Median	2.0	1.0	2.0	1.0	
Min, Max	1, 3	0, 3	0, 4	0, 4	
C5D1 CFB					
n	3	8	55	97	
LS Mean (StdErr) [2]	0.28 (1.189)	-0.63 (1.050)	-0.29 (0.167)	-0.68 (0.132)	
95% CI [2]	-2.53, 3.10	-3.11, 1.85	-0.62, 0.04	-0.94, -0.42	
Difference (95% CI) in CFB [2]		-0.92 (-4.15, 2.32)		-0.39 (-0.75, -0.02)	
p-value [3]		0.524		0.037	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-thpy-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	55	102	
Mean (StdDev)	2.7 (0.58)	1.2 (0.83)	1.7 (1.22)	1.5 (1.25)	
Median	3.0	1.0	2.0	1.5	
Min, Max	2, 3	0, 3	0, 4	0, 4	
C6D1 CFB					
n	3	9	53	98	
LS Mean (StdErr) [2]	0.61 (0.669)	-1.29 (0.591)	-0.26 (0.182)	-0.78 (0.142)	
95% CI [2]	-0.93, 2.15	-2.66, 0.07	-0.62, 0.10	-1.06, -0.50	
Difference (95% CI) in CFB [2]		-1.91 (-3.67, -0.14)		-0.52 (-0.91, -0.12)	
p-value [3]		0.038		0.011	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-thpy-a.sas Date: 16:05/07AUG2023

Table 35.2.12.2.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

MCQOL-Sad	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	8	55	103	
Mean (StdDev)	2.0 (1.00)	1.3 (0.89)	1.7 (1.20)	1.6 (1.29)	
Median	2.0	1.0	2.0	2.0	
Min, Max	1, 3	0, 3	0, 4	0, 4	
C7D1 CFB					
n	3	8	53	99	
LS Mean (StdErr) [2]	0.03 (0.863)	-1.31 (0.762)	-0.09 (0.189)	-0.51 (0.146)	
95% CI [2]	-2.01, 2.07	-3.11, 0.50	-0.47, 0.28	-0.79, -0.22	
Difference (95% CI) in CFB [2]		-1.33 (-3.68, 1.01)		-0.41 (-0.82, -0.01)	
Hedges'G (95% CI) in CFB		-0.60 (-2.34, 0.79)		-0.29 (-0.63, 0.05)	
p-value [3]		0.221		0.046	
					0.301

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-pp-thpy-a.sas Date: 16:05/07AUG2023

Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	53	113	11	6	
Mean (StdDev)	37.15 (12.079)	36.93 (11.380)	42.74 (12.634)	32.67 (9.836)	
Median	39.69	39.69	48.10	31.27	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 48.1	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-age-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	54	113	11	6	
Mean (StdDev)	38.91 (11.356)	39.83 (11.951)	45.04 (7.778)	41.09 (12.385)	
Median	39.69	39.69	48.10	43.89	
Min, Max	22.9, 56.5	22.9, 56.5	31.3, 56.5	22.9, 56.5	
C2D1 CFB					
n	51	110	11	6	
LS Mean (StdErr) [2]	1.23 (1.138)	2.15 (0.827)	-0.07 (5.383)	1.08 (7.848)	
95% CI [2]	-1.02, 3.48	0.51, 3.78	-11.70, 11.56	-15.88, 18.03	
Difference (95% CI) in CFB [2]		0.92 (-1.48, 3.32)		1.15 (-12.04, 14.34)	
p-value [3]		0.450		0.854	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	53	104	10	6	
Mean (StdDev)	38.26 (10.402)	40.33 (12.054)	43.05 (9.045)	41.09 (13.480)	
Median	39.69	39.69	39.69	39.69	
Min, Max	22.9, 56.5	22.9, 56.5	31.3, 56.5	22.9, 56.5	
C3D1 CFB					
n	50	103	10	6	
LS Mean (StdErr) [2]	1.30 (1.191)	3.24 (0.855)	-1.48 (5.015)	2.47 (7.252)	
95% CI [2]	-1.06, 3.65	1.55, 4.93	-12.41, 9.44	-13.33, 18.27	
Difference (95% CI) in CFB [2]		1.95 (-0.56, 4.46)		3.96 (-8.37, 16.29)	
p-value [3]		0.128		0.497	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	49	107	7	6	
Mean (StdDev)	38.83 (10.621)	40.63 (11.576)	42.09 (12.588)	41.09 (11.184)	
Median	39.69	39.69	39.69	48.10	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 48.1	
C4D1 CFB					
n	46	105	7	6	
LS Mean (StdErr) [2]	3.27 (1.404)	4.27 (0.995)	-2.73 (3.783)	4.84 (6.205)	
95% CI [2]	0.50, 6.05	2.30, 6.23	-11.29, 5.82	-9.20, 18.87	
Difference (95% CI) in CFB [2]		0.99 (-1.89, 3.88)		7.57 (-4.61, 19.76)	
p-value [3]		0.497		0.193	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-age-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	51	104	9	5	
Mean (StdDev)	39.52 (12.536)	41.06 (11.790)	41.56 (10.953)	36.32 (9.593)	
Median	39.69	39.69	39.69	39.69	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 48.1	
C5D1 CFB					
n	49	100	9	5	
LS Mean (StdErr) [2]	1.84 (1.359)	4.66 (0.986)	-2.19 (4.232)	-5.12 (6.499)	
95% CI [2]	-0.85, 4.52	2.71, 6.61	-11.62, 7.23	-19.60, 9.36	
Difference (95% CI) in CFB [2]		2.82 (-0.03, 5.68)		-2.93 (-14.80, 8.94)	
p-value [3]		0.053		0.595	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	50	105	8	6	
Mean (StdDev)	38.00 (11.529)	42.25 (12.300)	42.84 (8.924)	39.69 (11.899)	
Median	39.69	39.69	39.69	39.69	
Min, Max	22.9, 56.5	22.9, 56.5	31.3, 56.5	22.9, 56.5	
C6D1 CFB					
n	48	101	8	6	
LS Mean (StdErr) [2]	0.93 (1.392)	5.15 (1.001)	-1.66 (3.631)	-3.67 (6.028)	
95% CI [2]	-1.82, 3.68	3.17, 7.12	-9.75, 6.43	-17.11, 9.76	
Difference (95% CI) in CFB [2]		4.22 (1.29, 7.14)		-2.01 (-13.60, 9.57)	
p-value [3]		0.005		0.706	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	48	105	10	6	
Mean (StdDev)	38.98 (10.955)	41.61 (12.140)	41.37 (13.035)	41.09 (12.385)	
Median	39.69	39.69	39.69	43.89	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C7D1 CFB					
n	46	101	10	6	
LS Mean (StdErr) [2]	0.75 (1.457)	3.86 (1.019)	-3.24 (6.091)	0.11 (8.808)	
95% CI [2]	-2.13, 3.63	1.84, 5.87	-16.52, 10.03	-19.08, 19.30	
Difference (95% CI) in CFB [2]		3.11 (0.08, 6.14)		3.35 (-11.62, 18.33)	
Hedges'G (95% CI) in CFB		0.31 (-0.04, 0.66)		0.16 (-0.92, 1.29)	
p-value [3]		0.044		0.634	
					0.273

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	53	113	11	6	
Mean (StdDev)	33.67 (7.422)	34.20 (8.625)	39.41 (8.388)	33.77 (5.967)	
Median	30.03	34.51	39.00	34.51	
Min, Max	21.0, 48.0	21.0, 57.0	30.0, 52.5	25.5, 39.0	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	54	113	11	6	
Mean (StdDev)	35.10 (9.395)	36.90 (10.253)	42.27 (8.300)	34.51 (5.679)	
Median	34.51	34.51	39.00	32.27	
Min, Max	21.0, 57.0	21.0, 57.0	30.0, 57.0	30.0, 43.5	
C2D1 CFB					
n	51	110	11	6	
LS Mean (StdErr) [2]	0.43 (1.172)	1.86 (0.852)	2.24 (2.293)	2.24 (3.343)	
95% CI [2]	-1.88, 2.75	0.18, 3.54	-2.71, 7.20	-4.98, 9.47	
Difference (95% CI) in CFB [2]		1.43 (-1.04, 3.90)		0.00 (-5.62, 5.62)	
p-value [3]		0.255		>0.999	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	53	104	10	6	
Mean (StdDev)	35.79 (9.457)	38.62 (10.526)	41.25 (10.843)	38.26 (5.248)	
Median	34.51	39.00	41.25	36.76	
Min, Max	21.0, 57.0	21.0, 57.0	21.0, 57.0	34.5, 48.0	
C3D1 CFB					
n	50	103	10	6	
LS Mean (StdErr) [2]	1.53 (1.250)	4.16 (0.897)	1.20 (3.188)	6.81 (4.610)	
95% CI [2]	-0.94, 4.00	2.39, 5.93	-5.74, 8.15	-3.24, 16.85	
Difference (95% CI) in CFB [2]		2.63 (-0.00, 5.27)		5.60 (-2.23, 13.44)	
p-value [3]		0.050		0.145	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	49	105	7	6	
Mean (StdDev)	35.89 (10.047)	39.18 (10.490)	40.29 (9.942)	44.24 (5.967)	
Median	34.51	39.00	39.00	43.49	
Min, Max	21.0, 57.0	21.0, 57.0	25.5, 52.5	34.5, 52.5	
C4D1 CFB					
n	46	103	7	6	
LS Mean (StdErr) [2]	1.95 (1.301)	4.62 (0.931)	0.15 (2.708)	11.82 (4.441)	
95% CI [2]	-0.62, 4.52	2.78, 6.46	-5.98, 6.27	1.78, 21.87	
Difference (95% CI) in CFB [2]		2.67 (-0.00, 5.35)		11.67 (2.95, 20.40)	
p-value [3]		0.050		0.014	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	51	104	9	5	
Mean (StdDev)	36.63 (8.904)	38.44 (10.120)	36.51 (11.248)	45.29 (7.512)	
Median	39.00	39.00	39.00	43.49	
Min, Max	21.0, 57.0	21.0, 57.0	21.0, 57.0	39.0, 57.0	
C5D1 CFB					
n	49	100	9	5	
LS Mean (StdErr) [2]	2.78 (1.157)	4.65 (0.839)	-2.00 (5.471)	12.54 (8.402)	
95% CI [2]	0.50, 5.07	2.99, 6.31	-14.19, 10.19	-6.18, 31.26	
Difference (95% CI) in CFB [2]		1.86 (-0.57, 4.29)		14.54 (-0.81, 29.89)	
p-value [3]		0.132		0.061	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	50	105	8	6	
Mean (StdDev)	35.14 (9.769)	40.29 (10.651)	38.44 (10.580)	42.00 (9.698)	
Median	34.51	39.00	36.76	45.74	
Min, Max	21.0, 57.0	21.0, 57.0	25.5, 57.0	30.0, 52.5	
C6D1 CFB					
n	48	101	8	6	
LS Mean (StdErr) [2]	0.80 (1.382)	5.65 (0.994)	1.04 (3.860)	8.88 (6.408)	
95% CI [2]	-1.94, 3.53	3.68, 7.61	-7.56, 9.64	-5.39, 23.16	
Difference (95% CI) in CFB [2]		4.85 (1.95, 7.76)		7.84 (-4.47, 20.15)	
p-value [3]		0.001		0.186	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	48	105	10	6	
Mean (StdDev)	37.04 (10.514)	40.20 (10.824)	41.25 (10.634)	41.25 (9.309)	
Median	36.76	39.00	39.00	41.25	
Min, Max	21.0, 57.0	21.0, 57.0	30.0, 57.0	25.5, 52.5	
C7D1 CFB					
n	46	101	10	6	
LS Mean (StdErr) [2]	2.29 (1.419)	5.24 (0.993)	1.03 (3.067)	9.10 (4.435)	
95% CI [2]	-0.51, 5.10	3.28, 7.20	-5.66, 7.71	-0.57, 18.76	
Difference (95% CI) in CFB [2]		2.95 (-0.00, 5.89)		8.07 (0.53, 15.61)	
Hedges'G (95% CI) in CFB		0.30 (-0.05, 0.65)		0.75 (-0.27, 2.03)	
p-value [3]		0.050		0.038	
					0.450

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	53	112	11	6	
Mean (StdDev)	30.84 (10.959)	31.41 (11.695)	40.00 (8.309)	31.13 (8.593)	
Median	26.00	26.00	36.27	26.00	
Min, Max	15.7, 56.8	15.7, 56.8	26.0, 56.8	26.0, 46.5	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	54	113	11	6	
Mean (StdDev)	34.56 (11.591)	38.09 (12.745)	41.87 (9.595)	34.56 (10.098)	
Median	36.27	36.27	36.27	31.13	
Min, Max	15.7, 56.8	15.7, 56.8	26.0, 56.8	26.0, 46.5	
C2D1 CFB					
n	51	109	11	6	
LS Mean (StdErr) [2]	1.79 (1.649)	4.78 (1.208)	1.17 (3.981)	3.03 (5.804)	
95% CI [2]	-1.46, 5.05	2.39, 7.16	-7.43, 9.77	-9.50, 15.57	
Difference (95% CI) in CFB [2]		2.99 (-0.49, 6.46)		1.87 (-7.89, 11.62)	
p-value [3]		0.092		0.686	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	53	104	10	6	
Mean (StdDev)	35.49 (11.367)	38.74 (12.269)	41.40 (8.728)	39.69 (8.386)	
Median	36.27	36.27	41.40	41.40	
Min, Max	15.7, 56.8	15.7, 56.8	26.0, 56.8	26.0, 46.5	
C3D1 CFB					
n	50	102	10	6	
LS Mean (StdErr) [2]	4.12 (1.521)	7.53 (1.101)	-0.34 (4.185)	4.36 (6.051)	
95% CI [2]	1.11, 7.13	5.36, 9.71	-9.45, 8.78	-8.82, 17.55	
Difference (95% CI) in CFB [2]		3.41 (0.20, 6.62)		4.70 (-5.59, 14.99)	
p-value [3]		0.037		0.339	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	49	106	7	6	
Mean (StdDev)	35.64 (10.975)	38.40 (12.892)	39.20 (11.428)	37.98 (7.731)	
Median	36.27	36.27	36.27	36.27	
Min, Max	15.7, 56.8	15.7, 56.8	26.0, 56.8	26.0, 46.5	
C4D1 CFB					
n	46	103	7	6	
LS Mean (StdErr) [2]	3.18 (1.748)	5.69 (1.270)	-2.23 (3.755)	3.94 (6.159)	
95% CI [2]	-0.27, 6.63	3.18, 8.20	-10.72, 6.27	-10.00, 17.87	
Difference (95% CI) in CFB [2]		2.51 (-1.06, 6.08)		6.16 (-5.93, 18.26)	
p-value [3]		0.166		0.279	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	51	104	9	5	
Mean (StdDev)	35.46 (12.298)	37.95 (13.125)	37.41 (13.036)	44.48 (13.391)	
Median	36.27	36.27	36.27	46.54	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 56.8	26.0, 56.8	
C5D1 CFB					
n	49	99	9	5	
LS Mean (StdErr) [2]	3.26 (1.675)	6.01 (1.225)	-3.57 (5.753)	5.36 (8.834)	
95% CI [2]	-0.05, 6.58	3.59, 8.43	-16.39, 9.25	-14.33, 25.04	
Difference (95% CI) in CFB [2]		2.75 (-0.78, 6.27)		8.93 (-7.21, 25.07)	
p-value [3]		0.125		0.246	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	49	105	8	6	
Mean (StdDev)	34.59 (12.812)	39.20 (12.953)	37.55 (13.929)	44.83 (12.007)	
Median	36.27	46.54	41.40	46.54	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 56.8	26.0, 56.8	
C6D1 CFB					
n	47	100	8	6	
LS Mean (StdErr) [2]	2.35 (1.692)	7.13 (1.221)	-2.53 (5.149)	12.37 (8.548)	
95% CI [2]	-1.00, 5.69	4.71, 9.54	-14.00, 8.94	-6.68, 31.41	
Difference (95% CI) in CFB [2]		4.78 (1.21, 8.34)		14.90 (-1.52, 31.32)	
p-value [3]		0.009		0.071	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	48	105	10	6	
Mean (StdDev)	36.48 (11.505)	38.91 (13.737)	41.40 (11.093)	41.40 (10.772)	
Median	36.27	36.27	41.40	41.40	
Min, Max	15.7, 56.8	15.7, 56.8	26.0, 56.8	26.0, 56.8	
C7D1 CFB					
n	46	100	10	6	
LS Mean (StdErr) [2]	2.36 (1.721)	4.88 (1.215)	-0.44 (4.471)	5.67 (6.465)	
95% CI [2]	-1.04, 5.76	2.48, 7.28	-10.18, 9.31	-8.41, 19.76	
Difference (95% CI) in CFB [2]		2.52 (-1.06, 6.09)		6.11 (-4.88, 17.10)	
Hedges'G (95% CI) in CFB		0.21 (-0.14, 0.56)		0.39 (-0.66, 1.58)	
p-value [3]		0.167		0.249	
					0.439

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	53	113	11	6	
Mean (StdDev)	32.93 (10.648)	33.50 (9.770)	39.12 (9.216)	30.05 (0.000)	
Median	30.05	30.05	44.92	30.05	
Min, Max	19.4, 61.9	19.4, 55.5	30.0, 55.5	30.0, 30.0	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	54	113	11	6	
Mean (StdDev)	34.77 (10.971)	35.48 (10.706)	42.79 (9.163)	28.27 (4.337)	
Median	30.05	30.05	44.92	30.05	
Min, Max	19.4, 55.5	19.4, 55.5	30.0, 55.5	19.4, 30.0	
C2D1 CFB					
n	51	110	11	6	
LS Mean (StdErr) [2]	1.25 (1.356)	2.05 (0.985)	0.88 (4.065)	-8.97 (5.927)	
95% CI [2]	-1.43, 3.93	0.11, 4.00	-7.90, 9.66	-21.77, 3.84	
Difference (95% CI) in CFB [2]		0.80 (-2.06, 3.66)		-9.85 (-19.81, 0.11)	
p-value [3]		0.581		0.052	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	53	104	10	6	
Mean (StdDev)	33.89 (9.763)	36.85 (11.244)	39.61 (10.798)	35.00 (7.680)	
Median	30.05	30.05	37.48	30.05	
Min, Max	19.4, 55.5	19.4, 61.9	30.0, 55.5	30.0, 44.9	
C3D1 CFB					
n	50	103	10	6	
LS Mean (StdErr) [2]	0.31 (1.504)	3.53 (1.080)	-1.24 (3.547)	1.19 (5.129)	
95% CI [2]	-2.67, 3.28	1.39, 5.66	-8.96, 6.49	-9.98, 12.37	
Difference (95% CI) in CFB [2]		3.22 (0.05, 6.39)		2.43 (-6.29, 11.15)	
p-value [3]		0.047		0.555	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	49	107	7	6	
Mean (StdDev)	35.29 (10.921)	36.72 (11.145)	40.06 (10.094)	37.48 (8.146)	
Median	30.05	30.05	44.92	37.48	
Min, Max	19.4, 61.9	19.4, 55.5	30.0, 55.5	30.0, 44.9	
C4D1 CFB					
n	46	105	7	6	
LS Mean (StdErr) [2]	1.19 (1.638)	2.72 (1.161)	-0.37 (3.133)	4.09 (5.138)	
95% CI [2]	-2.05, 4.42	0.43, 5.02	-7.46, 6.72	-7.53, 15.71	
Difference (95% CI) in CFB [2]		1.54 (-1.83, 4.90)		4.46 (-5.63, 14.55)	
p-value [3]		0.369		0.343	

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Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	51	104	9	5	
Mean (StdDev)	35.88 (10.647)	37.36 (10.905)	36.66 (7.838)	35.99 (8.146)	
Median	30.05	44.92	30.05	30.05	
Min, Max	19.4, 61.9	19.4, 55.5	30.0, 44.9	30.0, 44.9	
C5D1 CFB					
n	49	100	9	5	
LS Mean (StdErr) [2]	2.72 (1.571)	3.92 (1.140)	-2.26 (3.609)	3.93 (5.542)	
95% CI [2]	-0.38, 5.83	1.66, 6.17	-10.30, 5.78	-8.42, 16.28	
Difference (95% CI) in CFB [2]		1.19 (-2.11, 4.49)		6.19 (-3.93, 16.31)	
p-value [3]		0.476		0.203	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	50	105	8	6	
Mean (StdDev)	35.44 (11.623)	38.16 (11.210)	38.81 (9.993)	37.48 (8.146)	
Median	30.05	44.92	37.48	37.48	
Min, Max	19.4, 61.9	19.4, 55.5	30.0, 55.5	30.0, 44.9	
C6D1 CFB					
n	48	101	8	6	
LS Mean (StdErr) [2]	1.81 (1.587)	4.69 (1.141)	-1.47 (3.673)	4.19 (6.098)	
95% CI [2]	-1.32, 4.95	2.43, 6.94	-9.65, 6.72	-9.40, 17.78	
Difference (95% CI) in CFB [2]		2.88 (-0.46, 6.21)		5.66 (-6.06, 17.37)	
p-value [3]		0.091		0.307	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	48	105	10	6	
Mean (StdDev)	35.36 (11.000)	38.75 (11.275)	41.09 (10.350)	37.48 (8.146)	
Median	30.05	44.92	44.92	37.48	
Min, Max	19.4, 55.5	19.4, 55.5	30.0, 55.5	30.0, 44.9	
C7D1 CFB					
n	46	101	10	6	
LS Mean (StdErr) [2]	0.60 (1.660)	4.28 (1.161)	-1.14 (3.695)	-0.07 (5.342)	
95% CI [2]	-2.68, 3.88	1.99, 6.58	-9.19, 6.91	-11.71, 11.57	
Difference (95% CI) in CFB [2]		3.68 (0.23, 7.13)		1.07 (-8.01, 10.15)	
Hedges'G (95% CI) in CFB		0.32 (-0.03, 0.68)		0.08 (-1.01, 1.21)	
p-value [3]		0.037		0.802	
					0.751

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	53	113	11	6	
Mean (StdDev)	38.43 (8.868)	37.13 (8.218)	43.57 (9.112)	31.75 (5.037)	
Median	38.25	38.25	48.00	28.50	
Min, Max	28.5, 57.8	28.5, 57.8	28.5, 57.8	28.5, 38.2	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	54	113	11	6	
Mean (StdDev)	39.33 (8.820)	39.28 (9.610)	46.23 (8.524)	35.00 (7.964)	
Median	38.25	38.25	48.00	33.37	
Min, Max	28.5, 57.8	28.5, 57.8	38.2, 67.5	28.5, 48.0	
C2D1 CFB					
n	51	110	11	6	
LS Mean (StdErr) [2]	0.96 (1.280)	2.76 (0.930)	-2.99 (3.442)	-3.88 (5.018)	
95% CI [2]	-1.57, 3.48	0.92, 4.60	-10.43, 4.44	-14.72, 6.96	
Difference (95% CI) in CFB [2]		1.80 (-0.90, 4.50)		-0.89 (-9.32, 7.55)	
p-value [3]		0.189		0.824	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	53	104	10	6	
Mean (StdDev)	40.64 (9.353)	40.31 (9.675)	46.05 (11.073)	38.25 (12.338)	
Median	38.25	38.25	48.00	33.37	
Min, Max	28.5, 57.8	28.5, 57.8	28.5, 67.5	28.5, 57.8	
C3D1 CFB					
n	50	103	10	6	
LS Mean (StdErr) [2]	2.92 (1.265)	3.81 (0.908)	5.39 (4.901)	8.00 (7.087)	
95% CI [2]	0.42, 5.42	2.02, 5.61	-5.29, 16.07	-7.44, 23.44	
Difference (95% CI) in CFB [2]		0.90 (-1.77, 3.56)		2.61 (-9.43, 14.66)	
p-value [3]		0.508		0.645	

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Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	49	107	7	6	
Mean (StdDev)	39.64 (8.209)	40.07 (10.127)	43.82 (11.060)	46.38 (11.403)	
Median	38.25	38.25	48.00	48.00	
Min, Max	28.5, 57.8	28.5, 57.8	28.5, 57.8	28.5, 57.8	
C4D1 CFB					
n	46	105	7	6	
LS Mean (StdErr) [2]	1.71 (1.536)	2.76 (1.089)	0.65 (4.427)	12.35 (7.261)	
95% CI [2]	-1.32, 4.75	0.61, 4.91	-9.36, 10.66	-4.07, 28.78	
Difference (95% CI) in CFB [2]		1.05 (-2.11, 4.20)		11.70 (-2.56, 25.97)	
p-value [3]		0.513		0.096	

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Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	51	104	9	5	
Mean (StdDev)	39.97 (9.296)	40.78 (10.079)	41.50 (9.754)	38.25 (9.754)	
Median	38.25	38.25	38.25	38.25	
Min, Max	28.5, 57.8	28.5, 67.5	28.5, 57.8	28.5, 48.0	
C5D1 CFB					
n	49	100	9	5	
LS Mean (StdErr) [2]	1.75 (1.458)	4.00 (1.058)	2.44 (7.023)	7.32 (10.786)	
95% CI [2]	-1.13, 4.63	1.91, 6.09	-13.21, 18.09	-16.72, 31.35	
Difference (95% CI) in CFB [2]		2.25 (-0.81, 5.31)		4.88 (-14.82, 24.58)	
p-value [3]		0.149		0.593	

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Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	50	105	8	6	
Mean (StdDev)	38.83 (9.118)	41.87 (10.145)	39.47 (8.140)	43.13 (13.445)	
Median	38.25	38.25	38.25	43.13	
Min, Max	28.5, 57.8	28.5, 67.5	28.5, 48.0	28.5, 57.8	
C6D1 CFB					
n	48	101	8	6	
LS Mean (StdErr) [2]	1.04 (1.439)	5.02 (1.034)	-2.40 (4.291)	1.99 (7.124)	
95% CI [2]	-1.80, 3.88	2.98, 7.07	-11.97, 7.16	-13.88, 17.87	
Difference (95% CI) in CFB [2]		3.98 (0.96, 7.01)		4.40 (-9.29, 18.08)	
p-value [3]		0.010		0.491	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	48	105	10	6	
Mean (StdDev)	40.28 (10.052)	41.31 (10.329)	46.05 (11.990)	41.50 (13.326)	
Median	38.25	38.25	48.00	38.25	
Min, Max	28.5, 57.8	28.5, 67.5	28.5, 67.5	28.5, 57.8	
C7D1 CFB					
n	46	101	10	6	
LS Mean (StdErr) [2]	2.24 (1.468)	3.74 (1.027)	4.62 (5.575)	8.19 (8.062)	
95% CI [2]	-0.66, 5.14	1.71, 5.77	-7.53, 16.77	-9.37, 25.76	
Difference (95% CI) in CFB [2]		1.50 (-1.55, 4.55)		3.57 (-10.13, 17.27)	
Hedges'G (95% CI) in CFB		0.15 (-0.20, 0.50)		0.18 (-0.90, 1.33)	
p-value [3]		0.333		0.581	
					0.294

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Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	53	113	11	6	
Mean (StdDev)	35.54 (12.119)	36.55 (10.881)	42.59 (8.021)	39.59 (5.120)	
Median	36.29	36.29	36.29	36.29	
Min, Max	16.5, 56.1	16.5, 56.1	36.3, 56.1	36.3, 46.2	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	54	113	11	6	
Mean (StdDev)	39.41 (10.518)	40.32 (11.673)	41.69 (11.185)	39.59 (5.120)	
Median	36.29	36.29	36.29	36.29	
Min, Max	16.5, 56.1	16.5, 56.1	26.4, 56.1	36.3, 46.2	
C2D1 CFB					
n	51	110	11	6	
LS Mean (StdErr) [2]	3.13 (1.600)	3.37 (1.162)	-0.14 (3.793)	2.11 (5.531)	
95% CI [2]	-0.03, 6.29	1.08, 5.67	-8.34, 8.05	-9.84, 14.06	
Difference (95% CI) in CFB [2]		0.24 (-3.13, 3.61)		2.25 (-7.04, 11.55)	
p-value [3]		0.888		0.609	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	53	104	10	6	
Mean (StdDev)	40.40 (11.574)	40.19 (11.997)	43.23 (9.405)	41.24 (8.295)	
Median	36.29	41.24	46.20	36.29	
Min, Max	16.5, 56.1	16.5, 56.1	26.4, 56.1	36.3, 56.1	
C3D1 CFB					
n	50	103	10	6	
LS Mean (StdErr) [2]	4.71 (1.554)	3.65 (1.115)	1.23 (5.146)	3.82 (7.441)	
95% CI [2]	1.64, 7.78	1.44, 5.85	-9.98, 12.44	-12.39, 20.04	
Difference (95% CI) in CFB [2]		-1.06 (-4.34, 2.21)		2.59 (-10.06, 15.24)	
p-value [3]		0.522		0.663	

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Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	49	107	7	6	
Mean (StdDev)	39.73 (11.001)	40.08 (12.529)	37.70 (12.045)	46.20 (8.867)	
Median	36.29	36.29	36.29	46.20	
Min, Max	16.5, 56.1	16.5, 56.1	16.5, 56.1	36.3, 56.1	
C4D1 CFB					
n	46	105	7	6	
LS Mean (StdErr) [2]	3.31 (1.810)	3.67 (1.283)	-1.16 (5.105)	12.72 (8.373)	
95% CI [2]	-0.27, 6.88	1.13, 6.20	-12.71, 10.39	-6.22, 31.66	
Difference (95% CI) in CFB [2]		0.36 (-3.36, 4.08)		13.88 (-2.57, 30.33)	
p-value [3]		0.849		0.089	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	51	104	9	5	
Mean (StdDev)	39.98 (12.055)	42.20 (12.319)	36.29 (9.914)	46.20 (9.914)	
Median	36.29	46.20	36.29	46.20	
Min, Max	16.5, 56.1	16.5, 56.1	26.4, 56.1	36.3, 56.1	
C5D1 CFB					
n	49	100	9	5	
LS Mean (StdErr) [2]	3.66 (1.803)	6.14 (1.308)	-3.88 (5.390)	0.86 (8.277)	
95% CI [2]	0.10, 7.22	3.56, 8.73	-15.89, 8.13	-17.58, 19.31	
Difference (95% CI) in CFB [2]		2.49 (-1.30, 6.27)		4.74 (-10.38, 19.86)	
p-value [3]		0.197		0.501	

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Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	50	105	8	6	
Mean (StdDev)	39.06 (11.686)	41.38 (12.229)	38.76 (11.550)	49.50 (8.095)	
Median	36.29	46.20	36.29	51.16	
Min, Max	16.5, 56.1	16.5, 56.1	26.4, 56.1	36.3, 56.1	
C6D1 CFB					
n	48	101	8	6	
LS Mean (StdErr) [2]	2.70 (1.894)	4.75 (1.361)	-1.54 (5.160)	10.05 (8.566)	
95% CI [2]	-1.05, 6.44	2.06, 7.44	-13.03, 9.96	-9.03, 29.14	
Difference (95% CI) in CFB [2]		2.05 (-1.93, 6.03)		11.59 (-4.87, 28.04)	
p-value [3]		0.311		0.148	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-age-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	48	105	10	6	
Mean (StdDev)	39.59 (11.983)	42.52 (12.843)	43.23 (11.495)	44.55 (7.463)	
Median	36.29	46.20	46.20	46.20	
Min, Max	16.5, 56.1	16.5, 56.1	26.4, 56.1	36.3, 56.1	
C7D1 CFB					
n	46	101	10	6	
LS Mean (StdErr) [2]	1.84 (1.899)	4.93 (1.329)	5.25 (4.708)	11.08 (6.808)	
95% CI [2]	-1.92, 5.59	2.30, 7.56	-5.01, 15.51	-3.75, 25.91	
Difference (95% CI) in CFB [2]		3.09 (-0.85, 7.04)		5.83 (-5.74, 17.41)	
Hedges'G (95% CI) in CFB		0.23 (-0.12, 0.59)		0.35 (-0.70, 1.53)	
p-value [3]		0.123		0.294	
					0.951

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	53	113	11	6	
Mean (StdDev)	36.67 (12.082)	37.61 (12.003)	40.27 (11.261)	37.43 (2.850)	
Median	33.75	39.27	39.27	39.27	
Min, Max	11.7, 55.8	11.7, 55.8	22.7, 55.8	33.8, 39.3	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	54	113	11	6	
Mean (StdDev)	39.78 (11.510)	40.74 (12.164)	40.78 (11.601)	42.95 (6.684)	
Median	39.27	44.79	39.27	39.27	
Min, Max	17.2, 55.8	11.7, 55.8	22.7, 55.8	39.3, 55.8	
C2D1 CFB					
n	51	110	11	6	
LS Mean (StdErr) [2]	3.28 (1.481)	3.36 (1.076)	-1.76 (3.705)	4.26 (5.402)	
95% CI [2]	0.36, 6.21	1.23, 5.48	-9.76, 6.25	-7.41, 15.93	
Difference (95% CI) in CFB [2]		0.08 (-3.04, 3.20)		6.02 (-3.06, 15.10)	
p-value [3]		0.960		0.176	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	53	104	10	6	
Mean (StdDev)	40.52 (12.698)	40.97 (12.186)	40.93 (11.936)	47.55 (9.069)	
Median	44.79	44.79	44.79	50.31	
Min, Max	11.7, 55.8	11.7, 55.8	22.7, 55.8	33.8, 55.8	
C3D1 CFB					
n	50	103	10	6	
LS Mean (StdErr) [2]	4.33 (1.569)	4.17 (1.126)	-4.64 (4.368)	5.07 (6.317)	
95% CI [2]	1.23, 7.43	1.95, 6.40	-14.15, 4.88	-8.70, 18.83	
Difference (95% CI) in CFB [2]		-0.16 (-3.47, 3.15)		9.70 (-1.03, 20.44)	
p-value [3]		0.924		0.072	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	49	106	7	6	
Mean (StdDev)	39.27 (12.341)	41.87 (12.287)	38.48 (12.103)	47.55 (9.717)	
Median	39.27	44.79	33.75	50.31	
Min, Max	17.2, 55.8	11.7, 55.8	22.7, 55.8	33.8, 55.8	
C4D1 CFB					
n	46	104	7	6	
LS Mean (StdErr) [2]	3.84 (1.790)	4.65 (1.269)	-3.50 (4.369)	5.33 (7.166)	
95% CI [2]	0.30, 7.38	2.15, 7.16	-13.38, 6.39	-10.88, 21.55	
Difference (95% CI) in CFB [2]		0.81 (-2.87, 4.49)		8.83 (-5.25, 22.91)	
p-value [3]		0.663		0.190	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	51	104	9	5	
Mean (StdDev)	41.87 (12.008)	42.30 (11.326)	33.14 (11.851)	49.21 (9.873)	
Median	44.79	44.79	33.75	55.83	
Min, Max	11.7, 55.8	11.7, 55.8	17.2, 55.8	33.8, 55.8	
C5D1 CFB					
n	49	100	9	5	
LS Mean (StdErr) [2]	4.85 (1.722)	4.80 (1.250)	-4.98 (6.747)	9.54 (10.362)	
95% CI [2]	1.44, 8.25	2.33, 7.27	-20.01, 10.05	-13.55, 32.63	
Difference (95% CI) in CFB [2]		-0.04 (-3.66, 3.58)		14.52 (-4.41, 33.44)	
p-value [3]		0.982		0.118	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	50	105	8	6	
Mean (StdDev)	40.71 (13.647)	41.06 (12.233)	39.27 (8.344)	49.39 (6.452)	
Median	44.79	44.79	33.75	50.31	
Min, Max	11.7, 55.8	11.7, 55.8	33.8, 55.8	39.3, 55.8	
C6D1 CFB					
n	48	101	8	6	
LS Mean (StdErr) [2]	3.02 (1.907)	2.74 (1.371)	-1.17 (4.319)	4.12 (7.170)	
95% CI [2]	-0.75, 6.79	0.03, 5.44	-10.79, 8.46	-11.86, 20.10	
Difference (95% CI) in CFB [2]		-0.28 (-4.29, 3.72)		5.29 (-8.49, 19.06)	
p-value [3]		0.888		0.413	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	48	105	10	6	
Mean (StdDev)	39.50 (12.675)	42.11 (11.958)	40.93 (14.022)	43.87 (8.842)	
Median	39.27	44.79	39.27	44.79	
Min, Max	11.7, 55.8	11.7, 55.8	11.7, 55.8	33.8, 55.8	
C7D1 CFB					
n	46	101	10	6	
LS Mean (StdErr) [2]	0.90 (1.684)	3.73 (1.178)	-1.35 (4.734)	1.03 (6.846)	
95% CI [2]	-2.43, 4.23	1.41, 6.06	-11.67, 8.96	-13.89, 15.94	
Difference (95% CI) in CFB [2]		2.83 (-0.67, 6.33)		2.38 (-9.26, 14.02)	
Hedges'G (95% CI) in CFB		0.24 (-0.11, 0.60)		0.14 (-0.94, 1.28)	
p-value [3]		0.112		0.664	
					0.705

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	53	113	11	6	
Mean (StdDev)	41.20 (9.253)	39.43 (9.905)	40.15 (11.035)	34.53 (4.579)	
Median	39.59	39.59	39.59	33.51	
Min, Max	27.4, 57.8	15.3, 63.9	21.3, 57.8	27.4, 39.6	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	54	113	11	6	
Mean (StdDev)	41.73 (10.380)	41.21 (10.568)	41.81 (10.632)	37.57 (3.141)	
Median	39.59	39.59	39.59	39.59	
Min, Max	21.3, 57.8	15.3, 57.8	27.4, 57.8	33.5, 39.6	
C2D1 CFB					
n	51	110	11	6	
LS Mean (StdErr) [2]	0.70 (1.159)	2.24 (0.842)	3.68 (2.390)	5.62 (3.484)	
95% CI [2]	-1.59, 2.99	0.58, 3.91	-1.48, 8.84	-1.91, 13.14	
Difference (95% CI) in CFB [2]		1.55 (-0.90, 3.99)		1.94 (-3.92, 7.79)	
p-value [3]		0.213		0.488	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	53	104	10	6	
Mean (StdDev)	42.35 (10.163)	43.10 (11.236)	42.03 (10.806)	45.68 (6.664)	
Median	39.59	45.68	39.59	45.68	
Min, Max	15.3, 63.9	15.3, 63.9	27.4, 57.8	39.6, 57.8	
C3D1 CFB					
n	50	103	10	6	
LS Mean (StdErr) [2]	1.30 (1.357)	4.14 (0.974)	1.07 (3.863)	10.38 (5.585)	
95% CI [2]	-1.38, 3.98	2.21, 6.06	-7.34, 9.49	-1.79, 22.55	
Difference (95% CI) in CFB [2]		2.83 (-0.03, 5.70)		9.30 (-0.19, 18.80)	
p-value [3]		0.052		0.054	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	49	107	7	6	
Mean (StdDev)	42.70 (9.628)	43.69 (11.047)	37.86 (9.755)	44.66 (8.954)	
Median	39.59	45.68	39.59	42.64	
Min, Max	27.4, 63.9	15.3, 63.9	21.3, 51.8	33.5, 57.8	
C4D1 CFB					
n	46	105	7	6	
LS Mean (StdErr) [2]	2.70 (1.435)	4.86 (1.017)	1.42 (5.204)	8.72 (8.536)	
95% CI [2]	-0.14, 5.53	2.85, 6.87	-10.35, 13.19	-10.59, 28.03	
Difference (95% CI) in CFB [2]		2.16 (-0.79, 5.11)		7.30 (-9.47, 24.07)	
p-value [3]		0.150		0.350	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	51	104	9	5	
Mean (StdDev)	43.17 (10.962)	43.28 (10.669)	37.57 (9.125)	44.46 (6.664)	
Median	39.59	45.68	39.59	39.59	
Min, Max	21.3, 63.9	15.3, 63.9	27.4, 57.8	39.6, 51.8	
C5D1 CFB					
n	49	100	9	5	
LS Mean (StdErr) [2]	2.51 (1.411)	4.61 (1.024)	-0.00 (6.020)	6.08 (9.245)	
95% CI [2]	-0.28, 5.30	2.58, 6.63	-13.41, 13.41	-14.52, 26.68	
Difference (95% CI) in CFB [2]		2.10 (-0.87, 5.07)		6.08 (-10.80, 22.97)	
p-value [3]		0.164		0.441	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	49	105	8	6	
Mean (StdDev)	43.19 (10.081)	42.61 (11.067)	39.59 (10.282)	44.66 (4.579)	
Median	39.59	45.68	36.55	45.68	
Min, Max	27.4, 63.9	15.3, 63.9	27.4, 57.8	39.6, 51.8	
C6D1 CFB					
n	47	101	8	6	
LS Mean (StdErr) [2]	1.66 (1.487)	3.79 (1.064)	2.14 (3.618)	8.65 (6.007)	
95% CI [2]	-1.28, 4.60	1.69, 5.89	-5.92, 10.20	-4.73, 22.04	
Difference (95% CI) in CFB [2]		2.12 (-1.01, 5.26)		6.51 (-5.03, 18.05)	
p-value [3]		0.182		0.237	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	48	105	10	6	
Mean (StdDev)	41.88 (10.840)	43.65 (12.186)	44.46 (10.259)	42.64 (6.380)	
Median	45.68	45.68	42.64	42.64	
Min, Max	15.3, 63.9	15.3, 63.9	27.4, 63.9	33.5, 51.8	
C7D1 CFB					
n	46	101	10	6	
LS Mean (StdErr) [2]	0.81 (1.753)	4.41 (1.226)	6.82 (4.110)	8.69 (5.943)	
95% CI [2]	-2.66, 4.27	1.98, 6.83	-2.14, 15.77	-4.26, 21.64	
Difference (95% CI) in CFB [2]		3.60 (-0.04, 7.24)		1.87 (-8.23, 11.97)	
Hedges'G (95% CI) in CFB		0.29 (-0.06, 0.65)		0.13 (-0.96, 1.26)	
p-value [3]		0.053		0.694	
					0.993

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	53	112	11	6	
Mean (StdDev)	32.84 (10.813)	33.26 (10.777)	41.23 (8.746)	31.36 (6.355)	
Median	31.33	33.47	42.94	30.35	
Min, Max	13.8, 60.4	10.5, 61.8	29.7, 56.2	23.5, 39.5	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	54	113	11	6	
Mean (StdDev)	34.92 (10.874)	37.17 (12.204)	44.34 (9.259)	34.20 (10.065)	
Median	34.97	37.77	46.30	36.77	
Min, Max	16.5, 61.2	13.0, 58.5	29.3, 60.0	19.0, 46.6	
C2D1 CFB					
n	51	109	11	6	
LS Mean (StdErr) [2]	0.71 (1.108)	2.55 (0.812)	0.79 (3.231)	-2.22 (4.711)	
95% CI [2]	-1.48, 2.90	0.95, 4.15	-6.19, 7.77	-12.39, 7.96	
Difference (95% CI) in CFB [2]		1.84 (-0.50, 4.18)		-3.00 (-10.92, 4.91)	
p-value [3]		0.122		0.427	

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Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	53	104	10	6	
Mean (StdDev)	34.72 (10.179)	38.10 (12.155)	42.10 (9.039)	36.23 (10.066)	
Median	34.48	39.17	43.14	38.96	
Min, Max	15.1, 62.6	13.3, 61.4	29.4, 60.0	20.8, 49.8	
C3D1 CFB					
n	50	102	10	6	
LS Mean (StdErr) [2]	1.28 (1.107)	4.36 (0.801)	0.18 (3.008)	2.06 (4.350)	
95% CI [2]	-0.91, 3.47	2.78, 5.94	-6.38, 6.73	-7.42, 11.54	
Difference (95% CI) in CFB [2]		3.08 (0.75, 5.42)		1.88 (-5.51, 9.28)	
p-value [3]		0.010		0.589	

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Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	49	104	7	6	
Mean (StdDev)	35.53 (10.599)	38.26 (11.810)	42.13 (11.463)	38.83 (8.138)	
Median	35.49	39.64	42.66	41.18	
Min, Max	10.8, 61.5	12.8, 59.8	26.6, 56.5	25.9, 46.4	
C4D1 CFB					
n	46	101	7	6	
LS Mean (StdErr) [2]	1.87 (1.272)	4.00 (0.934)	-1.52 (2.735)	5.78 (4.486)	
95% CI [2]	-0.65, 4.38	2.15, 5.85	-7.71, 4.67	-4.36, 15.93	
Difference (95% CI) in CFB [2]		2.13 (-0.47, 4.74)		7.31 (-1.51, 16.12)	
p-value [3]		0.107		0.093	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	51	104	9	5	
Mean (StdDev)	35.58 (11.377)	37.93 (12.301)	40.19 (10.893)	38.36 (11.776)	
Median	36.03	38.60	40.79	35.51	
Min, Max	13.5, 60.1	13.0, 64.3	26.8, 53.1	24.8, 53.6	
C5D1 CFB					
n	49	99	9	5	
LS Mean (StdErr) [2]	1.85 (1.160)	4.43 (0.849)	-2.28 (4.187)	1.94 (6.431)	
95% CI [2]	-0.45, 4.14	2.75, 6.11	-11.61, 7.05	-12.39, 16.27	
Difference (95% CI) in CFB [2]		2.58 (0.15, 5.02)		4.22 (-7.53, 15.97)	
p-value [3]		0.038		0.442	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	49	105	8	6	
Mean (StdDev)	34.42 (11.160)	40.10 (12.109)	40.30 (10.790)	39.15 (12.242)	
Median	32.98	41.63	41.12	38.79	
Min, Max	16.4, 58.8	17.3, 61.0	28.1, 58.1	22.7, 54.5	
C6D1 CFB					
n	47	100	8	6	
LS Mean (StdErr) [2]	0.89 (1.257)	6.18 (0.907)	-1.81 (2.663)	3.82 (4.421)	
95% CI [2]	-1.60, 3.37	4.39, 7.97	-7.75, 4.12	-6.04, 13.67	
Difference (95% CI) in CFB [2]		5.29 (2.64, 7.94)		5.63 (-2.86, 14.12)	
p-value [3]		<0.001		0.171	

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Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	48	105	10	6	
Mean (StdDev)	36.44 (11.218)	39.39 (12.348)	41.22 (10.800)	39.89 (11.406)	
Median	36.70	39.13	38.61	40.84	
Min, Max	14.5, 63.2	12.5, 63.1	27.1, 57.1	23.4, 55.1	
C7D1 CFB					
n	46	100	10	6	
LS Mean (StdErr) [2]	1.60 (1.283)	4.41 (0.906)	-2.59 (3.757)	3.06 (5.433)	
95% CI [2]	-0.93, 4.14	2.62, 6.20	-10.78, 5.60	-8.77, 14.90	
Difference (95% CI) in CFB [2]		2.81 (0.14, 5.47)		5.65 (-3.58, 14.89)	
Hedges'G (95% CI) in CFB		0.31 (-0.04, 0.67)		0.43 (-0.62, 1.63)	
p-value [3]		0.039		0.207	
					0.229

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-age-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
Baseline					
n	53	112	11	6	
Mean (StdDev)	40.40 (10.586)	40.03 (10.290)	41.61 (10.556)	38.07 (3.181)	
Median	39.00	39.58	42.89	38.34	
Min, Max	19.2, 58.7	13.2, 61.2	26.8, 57.5	33.6, 41.9	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C2D1					
n	54	113	11	6	
Mean (StdDev)	42.32 (10.656)	41.93 (10.676)	41.89 (12.617)	40.37 (5.103)	
Median	42.36	42.27	41.51	39.25	
Min, Max	19.9, 64.4	19.0, 64.8	23.2, 58.2	35.1, 47.3	
C2D1 CFB					
n	51	109	11	6	
LS Mean (StdErr) [2]	2.25 (1.257)	2.71 (0.921)	-0.10 (3.045)	3.56 (4.439)	
95% CI [2]	-0.23, 4.74	0.89, 4.52	-6.68, 6.47	-6.03, 13.15	
Difference (95% CI) in CFB [2]		0.45 (-2.20, 3.10)		3.66 (-3.80, 11.12)	
p-value [3]		0.737		0.309	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C3D1					
n	53	104	10	6	
Mean (StdDev)	43.50 (11.081)	42.74 (10.665)	43.12 (11.091)	46.45 (6.858)	
Median	43.72	44.47	43.86	49.20	
Min, Max	11.2, 63.3	13.8, 66.0	28.6, 61.6	36.5, 53.9	
C3D1 CFB					
n	50	102	10	6	
LS Mean (StdErr) [2]	3.58 (1.323)	3.60 (0.958)	0.35 (3.233)	8.30 (4.675)	
95% CI [2]	0.97, 6.20	1.71, 5.50	-6.69, 7.40	-1.89, 18.49	
Difference (95% CI) in CFB [2]		0.02 (-2.77, 2.81)		7.95 (-0.00, 15.89)	
p-value [3]		0.988		0.050	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-age-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C4D1					
n	49	104	7	6	
Mean (StdDev)	42.53 (9.977)	43.42 (10.972)	38.57 (11.296)	48.60 (11.315)	
Median	41.23	43.83	36.48	49.76	
Min, Max	22.0, 59.7	13.7, 63.9	22.1, 55.7	31.0, 60.9	
C4D1 CFB					
n	46	101	7	6	
LS Mean (StdErr) [2]	3.12 (1.515)	4.08 (1.112)	-0.15 (4.970)	9.86 (8.152)	
95% CI [2]	0.13, 6.12	1.88, 6.28	-11.40, 11.09	-8.58, 28.30	
Difference (95% CI) in CFB [2]		0.96 (-2.14, 4.06)		10.01 (-6.00, 26.03)	
p-value [3]		0.543		0.191	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-age-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C5D1					
n	51	104	9	5	
Mean (StdDev)	43.80 (11.630)	43.98 (10.810)	36.00 (10.772)	47.66 (10.850)	
Median	45.32	44.97	38.48	47.64	
Min, Max	14.1, 61.6	19.5, 64.4	18.6, 54.6	31.4, 57.8	
C5D1 CFB					
n	49	99	9	5	
LS Mean (StdErr) [2]	3.64 (1.501)	4.67 (1.098)	-1.50 (7.420)	8.10 (11.395)	
95% CI [2]	0.67, 6.61	2.50, 6.84	-18.03, 15.04	-17.29, 33.49	
Difference (95% CI) in CFB [2]		1.03 (-2.12, 4.19)		9.59 (-11.22, 30.41)	
p-value [3]		0.519		0.329	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C6D1					
n	49	105	8	6	
Mean (StdDev)	43.63 (10.958)	42.52 (11.209)	39.25 (8.892)	49.45 (7.092)	
Median	42.30	43.15	37.34	50.44	
Min, Max	24.1, 61.4	12.1, 61.5	29.6, 55.6	39.6, 57.6	
C6D1 CFB					
n	47	100	8	6	
LS Mean (StdErr) [2]	2.68 (1.598)	2.78 (1.153)	0.08 (3.172)	7.64 (5.266)	
95% CI [2]	-0.48, 5.84	0.50, 5.06	-6.99, 7.15	-4.09, 19.38	
Difference (95% CI) in CFB [2]		0.10 (-3.27, 3.47)		7.57 (-2.55, 17.68)	
p-value [3]		0.954		0.127	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.1a
Change from Baseline of SF-12 by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Age <65 years		Age >=65 years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	Test of Interaction p-value [1]
C7D1					
n	48	105	10	6	
Mean (StdDev)	42.09 (11.763)	43.83 (11.730)	44.66 (10.493)	44.46 (8.893)	
Median	42.44	44.53	45.48	43.86	
Min, Max	12.1, 64.6	12.0, 63.3	31.2, 64.9	33.3, 54.7	
C7D1 CFB					
n	46	100	10	6	
LS Mean (StdErr) [2]	1.16 (1.621)	3.93 (1.144)	5.90 (4.056)	7.87 (5.865)	
95% CI [2]	-2.05, 4.36	1.66, 6.19	-2.93, 14.74	-4.90, 20.65	
Difference (95% CI) in CFB [2]		2.77 (-0.60, 6.14)		1.97 (-8.00, 11.94)	
Hedges'G (95% CI) in CFB		0.24 (-0.11, 0.60)		0.14 (-0.95, 1.27)	
p-value [3]		0.107		0.674	
					0.989

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	14	32	50	87	
Mean (StdDev)	38.48 (10.874)	39.69 (11.899)	38.00 (12.721)	35.62 (10.953)	
Median	39.69	39.69	39.69	31.27	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	14	33	51	86	
Mean (StdDev)	40.29 (10.676)	43.25 (11.334)	39.85 (11.224)	38.61 (11.955)	
Median	39.69	48.10	39.69	39.69	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C2D1 CFB					
n	13	31	49	85	
LS Mean (StdErr) [2]	1.26 (2.160)	2.94 (1.429)	1.16 (1.272)	1.91 (1.064)	
95% CI [2]	-3.10, 5.63	0.06, 5.83	-1.36, 3.67	-0.19, 4.02	
Difference (95% CI) in CFB [2]		1.68 (-3.06, 6.42)		0.75 (-1.97, 3.47)	
p-value [3]		0.477		0.584	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	28	48	82	
Mean (StdDev)	37.44 (8.087)	42.99 (11.974)	39.51 (10.907)	39.48 (12.043)	
Median	39.69	39.69	39.69	39.69	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C3D1 CFB					
n	14	28	46	81	
LS Mean (StdErr) [2]	-1.29 (2.193)	3.22 (1.540)	1.25 (1.308)	3.07 (1.056)	
95% CI [2]	-5.73, 3.15	0.10, 6.34	-1.34, 3.84	0.97, 5.16	
Difference (95% CI) in CFB [2]		4.51 (-0.34, 9.37)		1.82 (-0.96, 4.60)	
p-value [3]		0.068		0.198	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	13	30	43	83	
Mean (StdDev)	38.39 (4.667)	43.05 (11.396)	39.49 (12.108)	39.79 (11.493)	
Median	39.69	39.69	39.69	39.69	
Min, Max	31.3, 48.1	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C4D1 CFB					
n	12	29	41	82	
LS Mean (StdErr) [2]	4.06 (2.383)	4.86 (1.646)	1.40 (1.548)	3.83 (1.214)	
95% CI [2]	-0.77, 8.89	1.53, 8.20	-1.66, 4.47	1.43, 6.24	
Difference (95% CI) in CFB [2]		0.80 (-4.36, 5.96)		2.43 (-0.79, 5.65)	
p-value [3]		0.756		0.138	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	31	45	78	
Mean (StdDev)	40.25 (12.096)	43.49 (11.463)	39.69 (12.428)	39.79 (11.704)	
Median	39.69	39.69	39.69	39.69	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C5D1 CFB					
n	14	28	44	77	
LS Mean (StdErr) [2]	2.36 (2.315)	4.30 (1.636)	0.82 (1.510)	4.32 (1.227)	
95% CI [2]	-2.33, 7.05	0.98, 7.61	-2.17, 3.81	1.89, 6.75	
Difference (95% CI) in CFB [2]		1.94 (-3.15, 7.02)		3.50 (0.27, 6.74)	
p-value [3]		0.446		0.034	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	13	32	45	79	
Mean (StdDev)	35.80 (4.366)	45.73 (10.521)	39.50 (12.491)	40.64 (12.638)	
Median	39.69	48.10	39.69	39.69	
Min, Max	31.3, 39.7	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C6D1 CFB					
n	12	29	44	78	
LS Mean (StdErr) [2]	0.06 (2.558)	6.16 (1.710)	0.44 (1.487)	4.56 (1.208)	
95% CI [2]	-5.12, 5.25	2.69, 9.62	-2.50, 3.39	2.16, 6.95	
Difference (95% CI) in CFB [2]		6.09 (0.52, 11.67)		4.11 (0.91, 7.32)	
p-value [3]		0.033		0.012	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	14	34	44	77	
Mean (StdDev)	37.28 (8.368)	43.64 (11.200)	40.07 (12.031)	40.67 (12.433)	
Median	39.69	39.69	39.69	39.69	
Min, Max	22.9, 48.1	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C7D1 CFB					
n	13	31	43	76	
LS Mean (StdErr) [2]	-0.61 (2.961)	4.45 (1.937)	0.07 (1.563)	3.39 (1.261)	
95% CI [2]	-6.60, 5.37	0.54, 8.37	-3.03, 3.17	0.90, 5.89	
Difference (95% CI) in CFB [2]		5.07 (-1.38, 11.51)		3.32 (0.04, 6.61)	
Hedges'G (95% CI) in CFB		0.46 (-0.19, 1.16)		0.31 (-0.07, 0.69)	
p-value [3]		0.120		0.047	
					0.550

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	14	32	50	87	
Mean (StdDev)	34.19 (6.217)	36.90 (8.532)	34.78 (8.283)	33.17 (8.304)	
Median	32.27	39.00	34.51	34.51	
Min, Max	25.5, 48.0	21.0, 48.0	21.0, 52.5	21.0, 57.0	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	14	33	51	86	
Mean (StdDev)	33.55 (7.298)	38.19 (9.286)	37.07 (10.009)	36.24 (10.356)	
Median	34.51	39.00	39.00	34.51	
Min, Max	21.0, 48.0	21.0, 52.5	21.0, 57.0	21.0, 57.0	
C2D1 CFB					
n	13	31	49	85	
LS Mean (StdErr) [2]	-1.24 (2.074)	0.98 (1.372)	1.37 (1.211)	2.22 (1.013)	
95% CI [2]	-5.43, 2.95	-1.79, 3.76	-1.03, 3.77	0.22, 4.23	
Difference (95% CI) in CFB [2]		2.23 (-2.33, 6.78)		0.85 (-1.74, 3.44)	
p-value [3]		0.329		0.516	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	28	48	82	
Mean (StdDev)	36.01 (8.596)	40.77 (9.171)	36.85 (10.228)	37.85 (10.601)	
Median	39.00	41.25	34.51	39.00	
Min, Max	21.0, 48.0	21.0, 52.5	21.0, 57.0	21.0, 57.0	
C3D1 CFB					
n	14	28	46	81	
LS Mean (StdErr) [2]	1.27 (2.425)	3.90 (1.703)	1.36 (1.278)	4.19 (1.032)	
95% CI [2]	-3.64, 6.18	0.45, 7.35	-1.17, 3.88	2.14, 6.23	
Difference (95% CI) in CFB [2]		2.62 (-2.74, 7.99)		2.83 (0.11, 5.55)	
p-value [3]		0.329		0.041	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	13	30	43	81	
Mean (StdDev)	33.13 (4.980)	40.65 (9.016)	37.44 (10.992)	39.00 (10.812)	
Median	34.51	41.25	39.00	39.00	
Min, Max	25.5, 43.5	25.5, 57.0	21.0, 57.0	21.0, 57.0	
C4D1 CFB					
n	12	29	41	80	
LS Mean (StdErr) [2]	0.54 (2.052)	4.75 (1.417)	1.68 (1.421)	4.64 (1.127)	
95% CI [2]	-3.62, 4.70	1.88, 7.62	-1.13, 4.50	2.41, 6.88	
Difference (95% CI) in CFB [2]		4.21 (-0.24, 8.66)		2.96 (0.00, 5.92)	
p-value [3]		0.063		0.050	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	31	45	78	
Mean (StdDev)	36.01 (7.714)	40.16 (8.825)	36.81 (9.696)	38.20 (10.553)	
Median	39.00	39.00	39.00	39.00	
Min, Max	21.0, 48.0	21.0, 57.0	21.0, 57.0	21.0, 57.0	
C5D1 CFB					
n	14	28	44	77	
LS Mean (StdErr) [2]	2.64 (2.132)	3.78 (1.507)	1.29 (1.317)	5.09 (1.070)	
95% CI [2]	-1.67, 6.96	0.73, 6.84	-1.32, 3.90	2.97, 7.20	
Difference (95% CI) in CFB [2]		1.14 (-3.54, 5.82)		3.79 (0.97, 6.62)	
p-value [3]		0.625		0.009	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	13	32	45	79	
Mean (StdDev)	33.82 (5.134)	40.83 (9.462)	36.11 (10.835)	40.20 (11.037)	
Median	34.51	39.00	34.51	39.00	
Min, Max	25.5, 43.5	21.0, 57.0	21.0, 57.0	21.0, 57.0	
C6D1 CFB					
n	12	29	44	78	
LS Mean (StdErr) [2]	0.87 (2.519)	4.40 (1.684)	0.09 (1.440)	5.97 (1.169)	
95% CI [2]	-4.23, 5.97	0.99, 7.81	-2.76, 2.94	3.66, 8.29	
Difference (95% CI) in CFB [2]		3.53 (-1.96, 9.02)		5.88 (2.78, 8.99)	
p-value [3]		0.200		<0.001	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	14	34	44	77	
Mean (StdDev)	35.48 (9.832)	40.85 (9.515)	38.49 (10.791)	40.00 (11.250)	
Median	34.51	39.00	39.00	39.00	
Min, Max	21.0, 57.0	21.0, 57.0	21.0, 57.0	21.0, 57.0	
C7D1 CFB					
n	13	31	43	76	
LS Mean (StdErr) [2]	1.38 (2.583)	3.67 (1.689)	2.15 (1.446)	6.06 (1.166)	
95% CI [2]	-3.84, 6.60	0.25, 7.08	-0.71, 5.02	3.75, 8.37	
Difference (95% CI) in CFB [2]		2.29 (-3.34, 7.91)		3.91 (0.87, 6.94)	
Hedges'G (95% CI) in CFB		0.24 (-0.42, 0.92)		0.39 (0.02, 0.78)	
p-value [3]		0.416		0.012	
					0.629

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	14	32	50	86	
Mean (StdDev)	32.60 (11.818)	35.63 (11.648)	32.37 (10.958)	29.82 (11.145)	
Median	31.13	36.27	26.00	26.00	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 56.8	15.7, 56.8	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	14	33	51	86	
Mean (StdDev)	37.74 (11.292)	38.45 (10.820)	35.26 (11.666)	37.70 (13.290)	
Median	36.27	36.27	36.27	36.27	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 56.8	15.7, 56.8	
C2D1 CFB					
n	13	31	49	84	
LS Mean (StdErr) [2]	4.56 (2.811)	2.08 (1.860)	1.03 (1.710)	5.67 (1.446)	
95% CI [2]	-1.12, 10.24	-1.67, 5.84	-2.36, 4.41	2.81, 8.53	
Difference (95% CI) in CFB [2]		-2.47 (-8.64, 3.70)		4.64 (0.99, 8.30)	
p-value [3]		0.423		0.013	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	28	48	82	
Mean (StdDev)	37.64 (12.193)	39.57 (11.877)	36.05 (10.904)	38.52 (12.187)	
Median	36.27	41.40	36.27	36.27	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 56.8	15.7, 56.8	
C3D1 CFB					
n	14	28	46	80	
LS Mean (StdErr) [2]	4.08 (2.448)	4.00 (1.719)	3.31 (1.593)	8.52 (1.301)	
95% CI [2]	-0.87, 9.04	0.52, 7.48	0.16, 6.47	5.95, 11.10	
Difference (95% CI) in CFB [2]		-0.08 (-5.50, 5.34)		5.21 (1.82, 8.60)	
p-value [3]		0.976		0.003	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	13	30	43	82	
Mean (StdDev)	37.85 (10.138)	39.35 (10.498)	35.55 (11.294)	38.02 (13.387)	
Median	36.27	41.40	36.27	36.27	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 56.8	15.7, 56.8	
C4D1 CFB					
n	12	29	41	80	
LS Mean (StdErr) [2]	5.31 (3.175)	3.20 (2.192)	1.15 (1.826)	6.16 (1.482)	
95% CI [2]	-1.12, 11.75	-1.24, 7.64	-2.47, 4.77	3.22, 9.09	
Difference (95% CI) in CFB [2]		-2.11 (-8.99, 4.77)		5.01 (1.24, 8.77)	
p-value [3]		0.538		0.010	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	31	45	78	
Mean (StdDev)	36.95 (11.944)	41.24 (10.564)	35.36 (12.545)	37.06 (13.925)	
Median	36.27	46.54	36.27	36.27	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 56.8	15.7, 56.8	
C5D1 CFB					
n	14	28	44	76	
LS Mean (StdErr) [2]	2.48 (3.155)	3.79 (2.230)	1.61 (1.798)	6.63 (1.476)	
95% CI [2]	-3.90, 8.87	-0.73, 8.30	-1.95, 5.17	3.71, 9.56	
Difference (95% CI) in CFB [2]		1.30 (-5.63, 8.23)		5.02 (1.17, 8.88)	
p-value [3]		0.706		0.011	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	13	32	44	79	
Mean (StdDev)	33.11 (11.394)	40.12 (10.991)	35.57 (13.363)	39.26 (13.676)	
Median	36.27	46.54	36.27	46.54	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 56.8	15.7, 56.8	
C6D1 CFB					
n	12	29	43	77	
LS Mean (StdErr) [2]	-0.13 (2.947)	3.23 (1.970)	1.75 (1.795)	8.71 (1.467)	
95% CI [2]	-6.10, 5.84	-0.76, 7.22	-1.81, 5.30	5.81, 11.62	
Difference (95% CI) in CFB [2]		3.36 (-3.06, 9.78)		6.97 (3.09, 10.85)	
p-value [3]		0.296		<0.001	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	14	34	44	77	
Mean (StdDev)	36.27 (9.008)	40.20 (12.130)	37.67 (12.251)	38.54 (14.198)	
Median	36.27	41.40	36.27	36.27	
Min, Max	26.0, 56.8	15.7, 56.8	15.7, 56.8	15.7, 56.8	
C7D1 CFB					
n	13	31	43	75	
LS Mean (StdErr) [2]	1.41 (2.905)	2.72 (1.900)	1.99 (1.826)	5.92 (1.491)	
95% CI [2]	-4.46, 7.29	-1.12, 6.56	-1.62, 5.61	2.96, 8.87	
Difference (95% CI) in CFB [2]		1.31 (-5.02, 7.63)		3.92 (0.09, 7.75)	
Hedges'G (95% CI) in CFB		0.12 (-0.54, 0.80)		0.31 (-0.07, 0.70)	
p-value [3]		0.679		0.045	
					0.459

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	14	32	50	87	
Mean (StdDev)	30.96 (8.729)	35.29 (10.643)	34.85 (11.009)	32.61 (9.073)	
Median	30.05	30.05	30.05	30.05	
Min, Max	19.4, 44.9	19.4, 55.5	19.4, 61.9	19.4, 55.5	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	14	33	51	86	
Mean (StdDev)	32.78 (8.797)	37.00 (10.371)	37.04 (11.491)	34.39 (10.640)	
Median	30.05	30.05	30.05	30.05	
Min, Max	19.4, 44.9	19.4, 55.5	19.4, 55.5	19.4, 55.5	
C2D1 CFB					
n	13	31	49	85	
LS Mean (StdErr) [2]	0.83 (1.956)	2.03 (1.294)	1.71 (1.511)	1.58 (1.264)	
95% CI [2]	-3.13, 4.78	-0.58, 4.65	-1.28, 4.70	-0.92, 4.08	
Difference (95% CI) in CFB [2]		1.21 (-3.09, 5.50)		-0.13 (-3.36, 3.10)	
p-value [3]		0.573		0.938	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	28	48	82	
Mean (StdDev)	30.61 (6.883)	37.33 (10.367)	36.11 (10.591)	36.55 (11.343)	
Median	30.05	30.05	30.05	30.05	
Min, Max	19.4, 44.9	19.4, 55.5	19.4, 55.5	19.4, 61.9	
C3D1 CFB					
n	14	28	46	81	
LS Mean (StdErr) [2]	-1.13 (2.230)	2.96 (1.566)	-0.10 (1.624)	3.25 (1.312)	
95% CI [2]	-5.64, 3.39	-0.21, 6.13	-3.31, 3.12	0.65, 5.85	
Difference (95% CI) in CFB [2]		4.09 (-0.84, 9.03)		3.35 (-0.10, 6.80)	
p-value [3]		0.101		0.057	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	13	30	43	83	
Mean (StdDev)	31.84 (8.402)	39.54 (10.872)	37.11 (11.287)	35.75 (10.909)	
Median	30.05	44.92	30.05	30.05	
Min, Max	19.4, 44.9	19.4, 55.5	19.4, 61.9	19.4, 55.5	
C4D1 CFB					
n	12	29	41	82	
LS Mean (StdErr) [2]	-1.28 (3.282)	5.01 (2.266)	1.00 (1.633)	1.59 (1.280)	
95% CI [2]	-7.93, 5.37	0.42, 9.61	-2.23, 4.24	-0.94, 4.13	
Difference (95% CI) in CFB [2]		6.30 (-0.82, 13.41)		0.59 (-2.81, 3.98)	
p-value [3]		0.081		0.732	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	31	45	78	
Mean (StdDev)	34.01 (9.221)	40.39 (10.562)	36.66 (10.548)	36.07 (10.666)	
Median	30.05	44.92	30.05	30.05	
Min, Max	19.4, 55.5	19.4, 55.5	19.4, 61.9	19.4, 55.5	
C5D1 CFB					
n	14	28	44	77	
LS Mean (StdErr) [2]	2.53 (2.915)	4.52 (2.061)	1.15 (1.651)	3.41 (1.342)	
95% CI [2]	-3.38, 8.43	0.34, 8.69	-2.12, 4.42	0.75, 6.07	
Difference (95% CI) in CFB [2]		1.99 (-4.41, 8.39)		2.26 (-1.28, 5.80)	
p-value [3]		0.533		0.209	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	13	32	45	79	
Mean (StdDev)	33.80 (8.235)	40.87 (10.730)	36.51 (12.162)	37.01 (11.034)	
Median	30.05	44.92	30.05	44.92	
Min, Max	19.4, 44.9	19.4, 55.5	19.4, 61.9	19.4, 55.5	
C6D1 CFB					
n	12	29	44	78	
LS Mean (StdErr) [2]	1.19 (3.187)	5.69 (2.131)	1.02 (1.603)	4.09 (1.301)	
95% CI [2]	-5.27, 7.64	1.37, 10.01	-2.15, 4.20	1.51, 6.67	
Difference (95% CI) in CFB [2]		4.50 (-2.44, 11.45)		3.07 (-0.39, 6.52)	
p-value [3]		0.197		0.081	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	14	34	44	77	
Mean (StdDev)	33.54 (7.976)	40.79 (10.155)	37.24 (11.764)	37.74 (11.436)	
Median	30.05	44.92	37.48	44.92	
Min, Max	19.4, 44.9	19.4, 55.5	19.4, 55.5	19.4, 55.5	
C7D1 CFB					
n	13	31	43	76	
LS Mean (StdErr) [2]	0.69 (2.869)	5.21 (1.876)	-0.09 (1.749)	3.51 (1.411)	
95% CI [2]	-5.10, 6.49	1.42, 9.01	-3.55, 3.38	0.71, 6.30	
Difference (95% CI) in CFB [2]		4.52 (-1.73, 10.77)		3.59 (-0.08, 7.27)	
Hedges'G (95% CI) in CFB		0.43 (-0.22, 1.12)		0.30 (-0.08, 0.68)	
p-value [3]		0.151		0.055	
					0.759

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	14	32	50	87	
Mean (StdDev)	36.86 (8.432)	36.73 (7.477)	40.00 (9.177)	36.90 (8.437)	
Median	38.25	38.25	38.25	38.25	
Min, Max	28.5, 48.0	28.5, 48.0	28.5, 57.8	28.5, 57.8	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	14	33	51	86	
Mean (StdDev)	40.34 (9.510)	37.95 (9.281)	40.54 (9.064)	39.50 (9.673)	
Median	38.25	38.25	38.25	38.25	
Min, Max	28.5, 57.8	28.5, 57.8	28.5, 67.5	28.5, 57.8	
C2D1 CFB					
n	13	31	49	85	
LS Mean (StdErr) [2]	2.96 (1.612)	1.65 (1.067)	0.61 (1.428)	3.09 (1.195)	
95% CI [2]	-0.30, 6.22	-0.50, 3.81	-2.21, 3.44	0.73, 5.46	
Difference (95% CI) in CFB [2]		-1.31 (-4.85, 2.23)		2.48 (-0.58, 5.53)	
p-value [3]		0.459		0.111	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	28	48	82	
Mean (StdDev)	38.90 (6.864)	41.04 (9.519)	42.31 (10.423)	39.91 (9.910)	
Median	38.25	38.25	43.13	38.25	
Min, Max	28.5, 57.8	28.5, 57.8	28.5, 67.5	28.5, 57.8	
C3D1 CFB					
n	14	28	46	81	
LS Mean (StdErr) [2]	1.20 (1.814)	4.56 (1.274)	3.08 (1.449)	3.63 (1.170)	
95% CI [2]	-2.47, 4.87	1.98, 7.14	0.22, 5.95	1.31, 5.95	
Difference (95% CI) in CFB [2]		3.36 (-0.66, 7.37)		0.55 (-2.53, 3.63)	
p-value [3]		0.099		0.726	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	13	30	43	83	
Mean (StdDev)	37.50 (7.409)	40.53 (9.475)	40.97 (8.860)	40.36 (10.559)	
Median	38.25	38.25	38.25	38.25	
Min, Max	28.5, 48.0	28.5, 57.8	28.5, 57.8	28.5, 57.8	
C4D1 CFB					
n	12	29	41	82	
LS Mean (StdErr) [2]	1.18 (2.340)	3.61 (1.616)	1.35 (1.767)	2.93 (1.385)	
95% CI [2]	-3.56, 5.92	0.33, 6.88	-2.15, 4.85	0.19, 5.67	
Difference (95% CI) in CFB [2]		2.43 (-2.64, 7.50)		1.58 (-2.09, 5.25)	
p-value [3]		0.338		0.396	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	31	45	78	
Mean (StdDev)	39.55 (10.978)	40.77 (9.069)	40.42 (8.795)	40.63 (10.449)	
Median	38.25	38.25	38.25	38.25	
Min, Max	28.5, 57.8	28.5, 57.8	28.5, 57.8	28.5, 67.5	
C5D1 CFB					
n	14	28	44	77	
LS Mean (StdErr) [2]	1.72 (2.024)	4.15 (1.430)	0.57 (1.747)	3.66 (1.419)	
95% CI [2]	-2.37, 5.82	1.26, 7.05	-2.89, 4.03	0.85, 6.48	
Difference (95% CI) in CFB [2]		2.43 (-2.02, 6.87)		3.10 (-0.65, 6.84)	
p-value [3]		0.275		0.104	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	13	32	45	79	
Mean (StdDev)	37.50 (7.409)	40.38 (9.510)	39.33 (9.351)	42.57 (10.564)	
Median	38.25	38.25	38.25	38.25	
Min, Max	28.5, 48.0	28.5, 57.8	28.5, 57.8	28.5, 67.5	
C6D1 CFB					
n	12	29	44	78	
LS Mean (StdErr) [2]	2.42 (2.014)	4.33 (1.347)	-0.72 (1.656)	5.14 (1.344)	
95% CI [2]	-1.66, 6.50	1.60, 7.05	-4.00, 2.56	2.48, 7.80	
Difference (95% CI) in CFB [2]		1.90 (-2.49, 6.29)		5.86 (2.29, 9.43)	
p-value [3]		0.386		0.001	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	14	34	44	77	
Mean (StdDev)	39.64 (10.724)	40.83 (8.760)	41.80 (10.537)	41.54 (11.145)	
Median	38.25	38.25	38.25	38.25	
Min, Max	28.5, 57.8	28.5, 57.8	28.5, 67.5	28.5, 67.5	
C7D1 CFB					
n	13	31	43	76	
LS Mean (StdErr) [2]	3.24 (2.058)	4.39 (1.346)	1.78 (1.723)	3.69 (1.389)	
95% CI [2]	-0.92, 7.40	1.67, 7.11	-1.63, 5.20	0.94, 6.44	
Difference (95% CI) in CFB [2]		1.15 (-3.33, 5.63)		1.91 (-1.71, 5.52)	
Hedges'G (95% CI) in CFB		0.15 (-0.51, 0.83)		0.16 (-0.22, 0.54)	
p-value [3]		0.607		0.298	
					0.795

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	14	32	50	87	
Mean (StdDev)	34.16 (11.121)	39.69 (8.580)	37.48 (11.957)	35.60 (11.191)	
Median	36.29	36.29	36.29	36.29	
Min, Max	16.5, 56.1	26.4, 56.1	16.5, 56.1	16.5, 56.1	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	14	33	51	86	
Mean (StdDev)	40.53 (8.443)	40.19 (9.895)	39.59 (11.158)	40.32 (12.011)	
Median	41.24	36.29	36.29	41.24	
Min, Max	26.4, 56.1	16.5, 56.1	16.5, 56.1	16.5, 56.1	
C2D1 CFB					
n	13	31	49	85	
LS Mean (StdErr) [2]	4.73 (2.282)	-0.00 (1.510)	1.98 (1.730)	4.65 (1.447)	
95% CI [2]	0.12, 9.34	-3.06, 3.05	-1.44, 5.41	1.78, 7.51	
Difference (95% CI) in CFB [2]		-4.73 (-9.74, 0.27)		2.66 (-1.04, 6.36)	
p-value [3]		0.063		0.157	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	28	48	82	
Mean (StdDev)	43.56 (10.903)	44.08 (8.254)	40.00 (11.318)	38.95 (12.564)	
Median	46.20	46.20	36.29	36.29	
Min, Max	16.5, 56.1	26.4, 56.1	16.5, 56.1	16.5, 56.1	
C3D1 CFB					
n	14	28	46	81	
LS Mean (StdErr) [2]	8.51 (2.725)	4.80 (1.914)	2.52 (1.644)	2.82 (1.328)	
95% CI [2]	3.00, 14.03	0.92, 8.67	-0.73, 5.77	0.19, 5.44	
Difference (95% CI) in CFB [2]		-3.72 (-9.75, 2.32)		0.30 (-3.20, 3.79)	
p-value [3]		0.220		0.867	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	13	30	43	83	
Mean (StdDev)	42.39 (10.349)	42.56 (10.570)	38.59 (11.208)	39.63 (12.980)	
Median	46.20	46.20	36.29	36.29	
Min, Max	26.4, 56.1	16.5, 56.1	16.5, 56.1	16.5, 56.1	
C4D1 CFB					
n	12	29	41	82	
LS Mean (StdErr) [2]	7.69 (3.175)	4.98 (2.192)	0.54 (1.945)	2.97 (1.525)	
95% CI [2]	1.26, 14.12	0.54, 9.42	-3.31, 4.39	-0.05, 5.99	
Difference (95% CI) in CFB [2]		-2.71 (-9.59, 4.17)		2.43 (-1.61, 6.47)	
p-value [3]		0.429		0.236	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	31	45	78	
Mean (StdDev)	41.57 (9.819)	45.88 (10.393)	38.71 (12.353)	40.99 (12.654)	
Median	36.29	46.20	36.29	46.20	
Min, Max	26.4, 56.1	26.4, 56.1	16.5, 56.1	16.5, 56.1	
C5D1 CFB					
n	14	28	44	77	
LS Mean (StdErr) [2]	4.55 (2.546)	4.96 (1.800)	1.11 (2.017)	6.01 (1.639)	
95% CI [2]	-0.60, 9.71	1.32, 8.60	-2.89, 5.10	2.76, 9.25	
Difference (95% CI) in CFB [2]		0.41 (-5.18, 6.00)		4.90 (0.57, 9.22)	
p-value [3]		0.883		0.027	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	13	32	45	79	
Mean (StdDev)	40.86 (10.410)	43.41 (10.146)	38.49 (11.936)	41.18 (12.885)	
Median	36.29	46.20	36.29	46.20	
Min, Max	26.4, 56.1	26.4, 56.1	16.5, 56.1	16.5, 56.1	
C6D1 CFB					
n	12	29	44	78	
LS Mean (StdErr) [2]	6.35 (2.695)	4.85 (1.802)	0.29 (2.087)	4.55 (1.695)	
95% CI [2]	0.89, 11.81	1.20, 8.50	-3.85, 4.42	1.19, 7.90	
Difference (95% CI) in CFB [2]		-1.50 (-7.37, 4.38)		4.26 (-0.24, 8.76)	
p-value [3]		0.608		0.063	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	14	34	44	77	
Mean (StdDev)	41.24 (12.750)	44.74 (8.845)	39.89 (11.729)	41.69 (13.886)	
Median	36.29	46.20	36.29	46.20	
Min, Max	26.4, 56.1	26.4, 56.1	16.5, 56.1	16.5, 56.1	
C7D1 CFB					
n	13	31	43	76	
LS Mean (StdErr) [2]	5.29 (2.740)	4.52 (1.792)	0.56 (2.085)	5.09 (1.681)	
95% CI [2]	-0.25, 10.83	0.90, 8.14	-3.57, 4.69	1.76, 8.42	
Difference (95% CI) in CFB [2]		-0.77 (-6.74, 5.19)		4.52 (0.15, 8.90)	
Hedges'G (95% CI) in CFB		-0.08 (-0.75, 0.59)		0.31 (-0.06, 0.70)	
p-value [3]		0.795		0.043	
					0.206

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	14	32	50	87	
Mean (StdDev)	38.09 (11.491)	39.62 (10.762)	37.06 (12.163)	36.86 (12.012)	
Median	33.75	39.27	33.75	33.75	
Min, Max	22.7, 55.8	17.2, 55.8	11.7, 55.8	11.7, 55.8	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	14	33	51	86	
Mean (StdDev)	38.09 (11.693)	41.28 (11.611)	40.46 (11.434)	40.68 (12.126)	
Median	36.51	44.79	39.27	42.03	
Min, Max	22.7, 55.8	11.7, 55.8	17.2, 55.8	11.7, 55.8	
C2D1 CFB					
n	13	31	49	85	
LS Mean (StdErr) [2]	0.41 (2.783)	1.47 (1.841)	3.97 (1.526)	4.43 (1.277)	
95% CI [2]	-5.22, 6.03	-2.25, 5.19	0.95, 6.99	1.90, 6.95	
Difference (95% CI) in CFB [2]		1.07 (-5.04, 7.17)		0.45 (-2.81, 3.72)	
p-value [3]		0.726		0.785	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	28	48	82	
Mean (StdDev)	41.11 (14.250)	43.61 (11.276)	40.42 (12.046)	40.55 (12.335)	
Median	44.79	44.79	39.27	44.79	
Min, Max	11.7, 55.8	22.7, 55.8	11.7, 55.8	11.7, 55.8	
C3D1 CFB					
n	14	28	46	81	
LS Mean (StdErr) [2]	2.07 (2.983)	4.25 (2.095)	4.02 (1.660)	4.41 (1.341)	
95% CI [2]	-3.97, 8.10	0.01, 8.49	0.74, 7.31	1.75, 7.06	
Difference (95% CI) in CFB [2]		2.18 (-4.42, 8.79)		0.38 (-3.14, 3.91)	
p-value [3]		0.507		0.830	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	13	30	43	82	
Mean (StdDev)	40.97 (11.352)	43.13 (11.147)	38.63 (12.528)	41.83 (12.603)	
Median	39.27	44.79	33.75	44.79	
Min, Max	22.7, 55.8	17.2, 55.8	17.2, 55.8	11.7, 55.8	
C4D1 CFB					
n	12	29	41	81	
LS Mean (StdErr) [2]	1.62 (3.178)	3.41 (2.194)	3.24 (1.926)	5.06 (1.510)	
95% CI [2]	-4.82, 8.06	-1.04, 7.85	-0.57, 7.06	2.07, 8.05	
Difference (95% CI) in CFB [2]		1.79 (-5.10, 8.67)		1.82 (-2.19, 5.83)	
p-value [3]		0.602		0.371	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	31	45	78	
Mean (StdDev)	40.74 (11.129)	44.08 (9.316)	40.50 (12.776)	42.03 (12.024)	
Median	39.27	44.79	39.27	44.79	
Min, Max	17.2, 55.8	22.7, 55.8	11.7, 55.8	11.7, 55.8	
C5D1 CFB					
n	14	28	44	77	
LS Mean (StdErr) [2]	1.18 (2.760)	2.78 (1.951)	3.47 (1.984)	5.51 (1.612)	
95% CI [2]	-4.40, 6.77	-1.17, 6.73	-0.46, 7.40	2.32, 8.70	
Difference (95% CI) in CFB [2]		1.59 (-4.47, 7.66)		2.04 (-2.21, 6.29)	
p-value [3]		0.598		0.344	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	13	32	45	79	
Mean (StdDev)	41.82 (9.456)	42.89 (10.264)	40.13 (13.920)	40.95 (12.817)	
Median	39.27	44.79	44.79	44.79	
Min, Max	28.2, 55.8	17.2, 55.8	11.7, 55.8	11.7, 55.8	
C6D1 CFB					
n	12	29	44	78	
LS Mean (StdErr) [2]	1.62 (3.514)	2.56 (2.349)	2.66 (2.018)	3.13 (1.639)	
95% CI [2]	-5.50, 8.74	-2.20, 7.32	-1.33, 6.66	-0.12, 6.37	
Difference (95% CI) in CFB [2]		0.95 (-6.71, 8.60)		0.47 (-3.89, 4.82)	
p-value [3]		0.804		0.833	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	14	34	44	77	
Mean (StdDev)	41.64 (13.642)	43.82 (10.389)	39.15 (12.624)	41.49 (12.349)	
Median	42.03	44.79	36.51	44.79	
Min, Max	11.7, 55.8	17.2, 55.8	11.7, 55.8	11.7, 55.8	
C7D1 CFB					
n	13	31	43	76	
LS Mean (StdErr) [2]	0.04 (2.828)	2.75 (1.850)	0.89 (1.806)	4.25 (1.456)	
95% CI [2]	-5.68, 5.75	-0.99, 6.49	-2.69, 4.46	1.36, 7.13	
Difference (95% CI) in CFB [2]		2.71 (-3.45, 8.87)		3.36 (-0.43, 7.15)	
Hedges'G (95% CI) in CFB		0.26 (-0.40, 0.94)		0.27 (-0.10, 0.65)	
p-value [3]		0.379		0.082	
					0.790

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	14	32	50	87	
Mean (StdDev)	41.33 (9.671)	38.83 (9.493)	40.93 (9.543)	39.31 (9.901)	
Median	39.59	39.59	39.59	39.59	
Min, Max	33.5, 57.8	15.3, 57.8	21.3, 57.8	15.3, 63.9	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	14	33	51	86	
Mean (StdDev)	43.50 (11.345)	39.41 (10.143)	41.26 (10.112)	41.65 (10.416)	
Median	42.64	39.59	39.59	39.59	
Min, Max	27.4, 57.8	15.3, 57.8	21.3, 57.8	15.3, 57.8	
C2D1 CFB					
n	13	31	49	85	
LS Mean (StdErr) [2]	0.67 (1.930)	0.26 (1.277)	1.32 (1.202)	3.30 (1.005)	
95% CI [2]	-3.23, 4.57	-2.32, 2.84	-1.06, 3.70	1.31, 5.28	
Difference (95% CI) in CFB [2]		-0.41 (-4.65, 3.82)		1.97 (-0.60, 4.54)	
p-value [3]		0.845		0.131	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	28	48	82	
Mean (StdDev)	42.03 (12.339)	42.42 (11.042)	42.38 (9.553)	43.53 (11.080)	
Median	39.59	45.68	39.59	45.68	
Min, Max	15.3, 57.8	21.3, 57.8	27.4, 63.9	15.3, 63.9	
C3D1 CFB					
n	14	28	46	81	
LS Mean (StdErr) [2]	-0.73 (2.935)	3.68 (2.061)	1.81 (1.354)	4.67 (1.094)	
95% CI [2]	-6.67, 5.22	-0.50, 7.85	-0.87, 4.50	2.50, 6.83	
Difference (95% CI) in CFB [2]		4.40 (-2.09, 10.90)		2.85 (-0.03, 5.73)	
p-value [3]		0.178		0.052	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	13	30	43	83	
Mean (StdDev)	42.87 (10.423)	42.64 (10.072)	41.86 (9.574)	44.14 (11.235)	
Median	39.59	45.68	39.59	45.68	
Min, Max	27.4, 57.8	21.3, 57.8	21.3, 63.9	15.3, 63.9	
C4D1 CFB					
n	12	29	41	82	
LS Mean (StdErr) [2]	-0.10 (2.624)	4.26 (1.812)	2.62 (1.576)	5.07 (1.235)	
95% CI [2]	-5.42, 5.21	0.59, 7.93	-0.50, 5.74	2.62, 7.51	
Difference (95% CI) in CFB [2]		4.37 (-1.32, 10.05)		2.44 (-0.83, 5.72)	
p-value [3]		0.128		0.142	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	31	45	78	
Mean (StdDev)	43.24 (12.339)	43.13 (8.854)	42.03 (10.408)	43.42 (11.140)	
Median	45.68	45.68	39.59	45.68	
Min, Max	21.3, 57.8	27.4, 57.8	21.3, 63.9	15.3, 63.9	
C5D1 CFB					
n	14	28	44	77	
LS Mean (StdErr) [2]	1.16 (2.432)	4.13 (1.719)	1.59 (1.624)	4.63 (1.320)	
95% CI [2]	-3.76, 6.09	0.65, 7.61	-1.63, 4.81	2.02, 7.25	
Difference (95% CI) in CFB [2]		2.96 (-2.38, 8.31)		3.04 (-0.44, 6.53)	
p-value [3]		0.269		0.086	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	13	32	44	79	
Mean (StdDev)	44.27 (9.981)	43.02 (9.765)	42.22 (10.196)	42.60 (11.270)	
Median	39.59	45.68	39.59	45.68	
Min, Max	33.5, 57.8	15.3, 57.8	27.4, 63.9	15.3, 63.9	
C6D1 CFB					
n	12	29	43	78	
LS Mean (StdErr) [2]	1.54 (2.972)	5.25 (1.987)	1.32 (1.536)	3.53 (1.243)	
95% CI [2]	-4.48, 7.56	1.23, 9.28	-1.72, 4.36	1.07, 5.99	
Difference (95% CI) in CFB [2]		3.71 (-2.77, 10.19)		2.21 (-1.11, 5.53)	
p-value [3]		0.253		0.190	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	14	34	44	77	
Mean (StdDev)	40.90 (12.439)	44.60 (9.409)	42.77 (10.203)	43.15 (12.917)	
Median	39.59	45.68	45.68	39.59	
Min, Max	15.3, 63.9	15.3, 57.8	21.3, 63.9	15.3, 63.9	
C7D1 CFB					
n	13	31	43	76	
LS Mean (StdErr) [2]	-1.07 (2.917)	6.55 (1.908)	2.05 (1.867)	3.65 (1.505)	
95% CI [2]	-6.97, 4.83	2.69, 10.40	-1.65, 5.75	0.67, 6.63	
Difference (95% CI) in CFB [2]		7.62 (1.27, 13.97)		1.60 (-2.32, 5.52)	
Hedges'G (95% CI) in CFB		0.71 (0.06, 1.43)		0.12 (-0.25, 0.50)	
p-value [3]		0.020		0.420	
					0.117

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	14	32	50	86	
Mean (StdDev)	33.23 (10.752)	36.95 (9.987)	34.58 (11.032)	31.75 (10.512)	
Median	32.27	37.70	33.69	31.14	
Min, Max	15.8, 51.4	19.3, 52.0	13.8, 60.4	10.5, 61.8	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	14	33	51	86	
Mean (StdDev)	35.43 (9.324)	39.82 (11.241)	36.81 (11.648)	35.94 (12.288)	
Median	36.13	42.38	35.38	35.81	
Min, Max	17.6, 47.9	18.5, 58.1	16.5, 61.2	13.0, 58.5	
C2D1 CFB					
n	13	31	49	84	
LS Mean (StdErr) [2]	1.57 (1.691)	2.47 (1.119)	0.61 (1.210)	2.31 (1.024)	
95% CI [2]	-1.84, 4.99	0.21, 4.73	-1.78, 3.01	0.29, 4.34	
Difference (95% CI) in CFB [2]		0.90 (-2.82, 4.61)		1.70 (-0.89, 4.29)	
p-value [3]		0.629		0.196	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	28	48	82	
Mean (StdDev)	34.19 (7.944)	40.00 (12.261)	36.42 (10.956)	37.31 (11.933)	
Median	33.29	39.21	36.90	38.94	
Min, Max	17.4, 52.2	15.3, 58.0	15.1, 62.6	13.3, 61.4	
C3D1 CFB					
n	14	28	46	80	
LS Mean (StdErr) [2]	0.65 (1.693)	3.21 (1.189)	0.78 (1.188)	4.35 (0.970)	
95% CI [2]	-2.78, 4.08	0.80, 5.62	-1.57, 3.13	2.43, 6.27	
Difference (95% CI) in CFB [2]		2.56 (-1.19, 6.31)		3.57 (1.04, 6.10)	
p-value [3]		0.174		0.006	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	13	30	43	80	
Mean (StdDev)	33.77 (5.357)	40.50 (11.369)	37.13 (11.943)	37.46 (11.665)	
Median	36.16	41.13	36.79	39.62	
Min, Max	21.4, 41.1	22.5, 59.8	10.8, 61.5	12.8, 57.4	
C4D1 CFB					
n	12	29	41	78	
LS Mean (StdErr) [2]	2.97 (1.804)	4.47 (1.246)	0.35 (1.425)	3.50 (1.172)	
95% CI [2]	-0.69, 6.62	1.94, 6.99	-2.47, 3.17	1.18, 5.82	
Difference (95% CI) in CFB [2]		1.50 (-2.41, 5.41)		3.15 (0.21, 6.09)	
p-value [3]		0.442		0.036	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	31	45	78	
Mean (StdDev)	35.85 (9.984)	41.02 (11.174)	36.41 (11.857)	36.72 (12.476)	
Median	36.03	39.23	38.22	38.12	
Min, Max	20.5, 51.4	18.5, 57.1	13.5, 60.1	13.0, 64.3	
C5D1 CFB					
n	14	28	44	76	
LS Mean (StdErr) [2]	2.88 (1.710)	4.12 (1.208)	0.37 (1.334)	4.29 (1.095)	
95% CI [2]	-0.58, 6.34	1.67, 6.56	-2.27, 3.01	2.12, 6.46	
Difference (95% CI) in CFB [2]		1.24 (-2.52, 4.99)		3.92 (1.06, 6.78)	
p-value [3]		0.508		0.008	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	13	32	44	79	
Mean (StdDev)	31.44 (6.708)	42.23 (11.067)	36.37 (12.054)	39.16 (12.399)	
Median	31.25	43.16	35.19	40.94	
Min, Max	19.6, 41.3	21.8, 61.0	16.4, 58.8	17.3, 59.1	
C6D1 CFB					
n	12	29	43	77	
LS Mean (StdErr) [2]	-0.04 (2.076)	5.04 (1.388)	0.12 (1.346)	6.32 (1.100)	
95% CI [2]	-4.25, 4.17	2.23, 7.85	-2.54, 2.79	4.15, 8.50	
Difference (95% CI) in CFB [2]		5.08 (0.55, 9.60)		6.20 (3.29, 9.11)	
p-value [3]		0.029		<0.0001	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	14	34	44	77	
Mean (StdDev)	34.42 (9.165)	40.84 (11.728)	38.17 (11.726)	38.80 (12.499)	
Median	34.18	39.41	37.41	39.13	
Min, Max	19.0, 51.2	15.4, 63.1	14.5, 63.2	12.5, 61.7	
C7D1 CFB					
n	13	31	43	75	
LS Mean (StdErr) [2]	1.13 (2.464)	3.46 (1.612)	0.68 (1.325)	4.68 (1.082)	
95% CI [2]	-3.85, 6.11	0.20, 6.72	-1.95, 3.30	2.54, 6.82	
Difference (95% CI) in CFB [2]		2.33 (-3.03, 7.70)		4.00 (1.22, 6.78)	
Hedges'G (95% CI) in CFB		0.26 (-0.40, 0.94)		0.44 (0.06, 0.83)	
p-value [3]		0.385		0.005	
					0.611

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
Baseline					
n	14	32	50	86	
Mean (StdDev)	39.86 (10.520)	39.79 (9.431)	40.82 (10.600)	39.98 (10.328)	
Median	37.54	40.49	39.71	38.69	
Min, Max	23.1, 58.6	23.4, 61.2	19.2, 58.7	13.2, 61.0	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C2D1					
n	14	33	51	86	
Mean (StdDev)	42.58 (10.887)	39.93 (10.686)	42.16 (11.017)	42.58 (10.340)	
Median	42.95	40.96	42.17	42.71	
Min, Max	20.8, 60.6	20.8, 62.2	19.9, 64.4	19.0, 64.8	
C2D1 CFB					
n	13	31	49	84	
LS Mean (StdErr) [2]	1.88 (2.195)	0.12 (1.453)	2.41 (1.301)	3.99 (1.100)	
95% CI [2]	-2.56, 6.32	-2.81, 3.06	-0.17, 4.98	1.81, 6.17	
Difference (95% CI) in CFB [2]		-1.76 (-6.58, 3.06)		1.58 (-1.20, 4.37)	
p-value [3]		0.465		0.262	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C3D1					
n	15	28	48	82	
Mean (StdDev)	44.04 (13.183)	43.80 (10.305)	43.25 (10.368)	42.65 (10.619)	
Median	43.25	44.98	43.95	44.84	
Min, Max	11.2, 60.6	25.8, 66.0	22.9, 63.3	13.8, 60.6	
C3D1 CFB					
n	14	28	46	80	
LS Mean (StdErr) [2]	2.87 (2.662)	4.34 (1.869)	3.26 (1.345)	3.63 (1.098)	
95% CI [2]	-2.51, 8.26	0.55, 8.12	0.60, 5.92	1.46, 5.80	
Difference (95% CI) in CFB [2]		1.46 (-4.43, 7.35)		0.37 (-2.49, 3.23)	
p-value [3]		0.618		0.799	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C4D1					
n	13	30	43	80	
Mean (StdDev)	43.85 (11.304)	43.17 (11.026)	41.49 (9.822)	43.90 (11.055)	
Median	42.33	43.81	41.05	44.67	
Min, Max	22.0, 59.4	23.4, 63.9	22.1, 59.7	13.7, 60.9	
C4D1 CFB					
n	12	29	41	78	
LS Mean (StdErr) [2]	1.50 (2.894)	3.64 (1.998)	2.76 (1.641)	4.42 (1.349)	
95% CI [2]	-4.37, 7.36	-0.41, 7.69	-0.49, 6.01	1.75, 7.09	
Difference (95% CI) in CFB [2]		2.14 (-4.12, 8.41)		1.66 (-1.72, 5.05)	
p-value [3]		0.493		0.333	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C5D1					
n	15	31	45	78	
Mean (StdDev)	43.46 (12.443)	44.52 (9.727)	42.35 (11.653)	43.99 (11.239)	
Median	42.70	44.91	41.38	45.37	
Min, Max	14.1, 59.4	27.4, 64.4	18.6, 61.6	19.5, 62.5	
C5D1 CFB					
n	14	28	44	76	
LS Mean (StdErr) [2]	1.56 (2.313)	3.63 (1.635)	2.28 (1.785)	4.92 (1.465)	
95% CI [2]	-3.12, 6.24	0.32, 6.94	-1.26, 5.81	2.02, 7.82	
Difference (95% CI) in CFB [2]		2.07 (-3.01, 7.15)		2.64 (-1.18, 6.47)	
p-value [3]		0.415		0.174	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C6D1					
n	13	32	44	79	
Mean (StdDev)	45.43 (9.688)	42.71 (9.887)	42.30 (11.023)	42.97 (11.635)	
Median	39.85	43.82	40.24	42.90	
Min, Max	34.4, 60.1	23.5, 61.4	24.1, 61.4	12.1, 61.5	
C6D1 CFB					
n	12	29	43	77	
LS Mean (StdErr) [2]	3.60 (2.889)	3.62 (1.931)	1.56 (1.704)	2.73 (1.393)	
95% CI [2]	-2.25, 9.45	-0.29, 7.54	-1.82, 4.93	-0.03, 5.49	
Difference (95% CI) in CFB [2]		0.02 (-6.27, 6.32)		1.17 (-2.52, 4.85)	
p-value [3]		0.994		0.532	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.2a
Change from Baseline of SF-12 by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Sex = Male		Sex = Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	Test of Interaction p-value [1]
C7D1					
n	14	34	44	77	
Mean (StdDev)	43.47 (13.503)	44.81 (8.862)	42.23 (10.957)	43.44 (12.603)	
Median	44.79	45.49	42.90	43.56	
Min, Max	12.1, 60.9	21.1, 63.3	21.3, 64.9	12.0, 62.7	
C7D1 CFB					
n	13	31	43	75	
LS Mean (StdErr) [2]	1.50 (2.532)	4.80 (1.657)	1.54 (1.766)	3.75 (1.441)	
95% CI [2]	-3.61, 6.62	1.45, 8.14	-1.96, 5.04	0.90, 6.61	
Difference (95% CI) in CFB [2]		3.29 (-2.22, 8.81)		2.21 (-1.49, 5.92)	
Hedges'G (95% CI) in CFB		0.35 (-0.30, 1.04)		0.18 (-0.20, 0.56)	
p-value [3]		0.234		0.239	
					0.808

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-sex-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	30	49	34	70	
Mean (StdDev)	40.25 (13.246)	37.97 (12.142)	36.22 (11.177)	35.84 (10.690)	
Median	39.69	39.69	35.48	31.27	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	30	51	35	68	
Mean (StdDev)	41.09 (12.119)	42.49 (12.328)	38.96 (10.074)	37.95 (11.313)	
Median	39.69	39.69	39.69	39.69	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C2D1 CFB					
n	28	48	34	68	
LS Mean (StdErr) [2]	0.58 (1.853)	4.16 (1.543)	1.80 (1.259)	0.91 (0.948)	
95% CI [2]	-3.11, 4.27	1.08, 7.23	-0.69, 4.30	-0.97, 2.79	
Difference (95% CI) in CFB [2]		3.58 (-0.51, 7.67)		-0.90 (-3.57, 1.78)	
p-value [3]		0.085		0.507	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-reg-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	29	44	34	66	
Mean (StdDev)	39.69 (10.548)	42.17 (12.777)	38.45 (10.176)	39.18 (11.516)	
Median	39.69	39.69	39.69	39.69	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C3D1 CFB					
n	27	43	33	66	
LS Mean (StdErr) [2]	0.62 (1.875)	4.74 (1.577)	1.06 (1.362)	2.40 (0.998)	
95% CI [2]	-3.13, 4.36	1.59, 7.89	-1.64, 3.77	0.42, 4.38	
Difference (95% CI) in CFB [2]		4.13 (-0.02, 8.27)		1.34 (-1.56, 4.23)	
p-value [3]		0.051		0.361	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-reg-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	22	44	34	69	
Mean (StdDev)	40.07 (11.750)	43.32 (11.534)	38.70 (10.308)	38.95 (11.246)	
Median	39.69	48.10	39.69	39.69	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C4D1 CFB					
n	20	43	33	68	
LS Mean (StdErr) [2]	4.03 (2.049)	7.97 (1.643)	1.49 (1.648)	2.54 (1.207)	
95% CI [2]	-0.07, 8.12	4.68, 11.26	-1.78, 4.76	0.15, 4.94	
Difference (95% CI) in CFB [2]		3.95 (-0.30, 8.19)		1.05 (-2.43, 4.54)	
p-value [3]		0.068		0.550	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-reg-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	26	41	34	68	
Mean (StdDev)	40.98 (13.185)	42.56 (10.907)	38.94 (11.601)	39.81 (12.119)	
Median	39.69	39.69	39.69	39.69	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C5D1 CFB					
n	25	38	33	67	
LS Mean (StdErr) [2]	2.21 (1.975)	7.58 (1.673)	0.95 (1.590)	2.67 (1.173)	
95% CI [2]	-1.74, 6.16	4.23, 10.93	-2.21, 4.11	0.34, 5.00	
Difference (95% CI) in CFB [2]		5.37 (0.97, 9.77)		1.72 (-1.65, 5.09)	
p-value [3]		0.018		0.313	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	24	44	34	67	
Mean (StdDev)	40.04 (11.764)	45.04 (10.901)	37.71 (10.972)	40.19 (12.759)	
Median	39.69	48.10	39.69	39.69	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C6D1 CFB					
n	23	41	33	66	
LS Mean (StdErr) [2]	0.75 (1.943)	8.02 (1.610)	0.34 (1.670)	3.33 (1.223)	
95% CI [2]	-3.13, 4.64	4.80, 11.24	-2.98, 3.65	0.90, 5.75	
Difference (95% CI) in CFB [2]		7.27 (2.95, 11.58)		2.99 (-0.56, 6.53)	
p-value [3]		0.001		0.098	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	24	44	34	67	
Mean (StdDev)	41.44 (12.888)	44.47 (10.796)	37.95 (9.886)	39.69 (12.600)	
Median	48.10	43.89	39.69	39.69	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C7D1 CFB					
n	23	41	33	66	
LS Mean (StdErr) [2]	-0.08 (2.026)	6.09 (1.622)	0.33 (1.853)	2.53 (1.357)	
95% CI [2]	-4.13, 3.97	2.85, 9.34	-3.34, 4.01	-0.16, 5.22	
Difference (95% CI) in CFB [2]		6.17 (1.91, 10.44)		2.20 (-1.74, 6.13)	
Hedges'G (95% CI) in CFB		0.60 (0.09, 1.15)		0.20 (-0.22, 0.63)	
p-value [3]		0.005		0.270	
					0.160

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	30	49	34	70	
Mean (StdDev)	35.86 (8.349)	36.26 (9.109)	33.59 (7.313)	32.72 (7.772)	
Median	34.51	34.51	30.03	34.51	
Min, Max	21.0, 48.0	21.0, 57.0	21.0, 52.5	21.0, 48.0	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	30	51	35	68	
Mean (StdDev)	38.70 (10.474)	38.83 (10.117)	34.26 (8.288)	35.24 (9.830)	
Median	39.00	39.00	34.51	34.51	
Min, Max	21.0, 57.0	21.0, 57.0	21.0, 52.5	21.0, 57.0	
C2D1 CFB					
n	28	48	34	68	
LS Mean (StdErr) [2]	1.40 (1.642)	1.34 (1.367)	0.17 (1.298)	2.19 (0.977)	
95% CI [2]	-1.87, 4.67	-1.39, 4.06	-2.40, 2.75	0.26, 4.13	
Difference (95% CI) in CFB [2]		-0.06 (-3.68, 3.56)		2.02 (-0.73, 4.77)	
p-value [3]		0.974		0.149	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	29	44	34	66	
Mean (StdDev)	39.31 (9.742)	39.72 (11.037)	34.38 (9.410)	37.85 (9.782)	
Median	39.00	39.00	34.51	39.00	
Min, Max	21.0, 57.0	21.0, 57.0	21.0, 52.5	21.0, 57.0	
C3D1 CFB					
n	27	43	33	66	
LS Mean (StdErr) [2]	2.50 (1.794)	2.96 (1.510)	0.44 (1.405)	4.95 (1.029)	
95% CI [2]	-1.08, 6.08	-0.05, 5.98	-2.35, 3.23	2.91, 7.00	
Difference (95% CI) in CFB [2]		0.46 (-3.50, 4.42)		4.51 (1.52, 7.49)	
p-value [3]		0.817		0.003	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	22	43	34	68	
Mean (StdDev)	39.62 (10.758)	42.45 (10.452)	34.38 (9.146)	37.55 (9.886)	
Median	39.00	43.49	34.51	39.00	
Min, Max	21.0, 57.0	21.0, 57.0	21.0, 52.5	21.0, 57.0	
C4D1 CFB					
n	20	42	33	67	
LS Mean (StdErr) [2]	4.01 (2.185)	5.32 (1.754)	0.25 (1.317)	4.49 (0.976)	
95% CI [2]	-0.36, 8.39	1.81, 8.83	-2.36, 2.87	2.55, 6.43	
Difference (95% CI) in CFB [2]		1.31 (-3.24, 5.85)		4.24 (1.45, 7.02)	
p-value [3]		0.568		0.003	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	26	41	34	68	
Mean (StdDev)	38.49 (10.341)	41.08 (9.315)	35.18 (8.056)	37.35 (10.346)	
Median	39.00	39.00	39.00	39.00	
Min, Max	21.0, 57.0	21.0, 57.0	21.0, 52.5	21.0, 57.0	
C5D1 CFB					
n	25	38	33	67	
LS Mean (StdErr) [2]	2.79 (1.762)	5.68 (1.493)	0.81 (1.480)	4.28 (1.092)	
95% CI [2]	-0.74, 6.32	2.69, 8.67	-2.12, 3.75	2.11, 6.45	
Difference (95% CI) in CFB [2]		2.89 (-1.04, 6.82)		3.46 (0.33, 6.60)	
p-value [3]		0.146		0.031	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	24	44	34	67	
Mean (StdDev)	38.26 (10.396)	44.21 (8.923)	33.72 (9.145)	37.87 (10.867)	
Median	36.76	45.74	34.51	39.00	
Min, Max	21.0, 57.0	21.0, 57.0	21.0, 57.0	21.0, 57.0	
C6D1 CFB					
n	23	41	33	66	
LS Mean (StdErr) [2]	1.77 (1.963)	7.02 (1.627)	-0.53 (1.613)	4.85 (1.182)	
95% CI [2]	-2.15, 5.70	3.76, 10.27	-3.73, 2.67	2.51, 7.20	
Difference (95% CI) in CFB [2]		5.24 (0.88, 9.61)		5.38 (1.95, 8.81)	
p-value [3]		0.019		0.002	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	24	44	34	67	
Mean (StdDev)	41.62 (10.910)	43.80 (9.797)	35.04 (9.556)	37.93 (10.718)	
Median	43.49	43.49	34.51	39.00	
Min, Max	21.0, 57.0	21.0, 57.0	21.0, 57.0	21.0, 57.0	
C7D1 CFB					
n	23	41	33	66	
LS Mean (StdErr) [2]	3.92 (2.098)	6.99 (1.680)	0.63 (1.559)	4.38 (1.142)	
95% CI [2]	-0.28, 8.11	3.63, 10.35	-2.47, 3.73	2.11, 6.64	
Difference (95% CI) in CFB [2]		3.07 (-1.35, 7.49)		3.75 (0.43, 7.06)	
Hedges'G (95% CI) in CFB		0.29 (-0.22, 0.82)		0.41 (-0.01, 0.84)	
p-value [3]		0.170		0.027	
					0.801

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	30	49	34	69	
Mean (StdDev)	34.90 (12.574)	33.96 (12.625)	30.23 (9.157)	29.57 (10.394)	
Median	36.27	26.00	26.00	26.00	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 46.5	15.7, 56.8	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	30	51	35	68	
Mean (StdDev)	37.98 (12.087)	40.30 (11.991)	33.92 (10.882)	36.12 (12.856)	
Median	36.27	46.54	36.27	36.27	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 56.8	15.7, 56.8	
C2D1 CFB					
n	28	48	34	67	
LS Mean (StdErr) [2]	1.27 (2.029)	4.49 (1.689)	2.23 (2.114)	4.88 (1.612)	
95% CI [2]	-2.77, 5.32	1.12, 7.85	-1.96, 6.43	1.68, 8.08	
Difference (95% CI) in CFB [2]		3.21 (-1.26, 7.69)		2.64 (-1.84, 7.13)	
p-value [3]		0.157		0.245	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	29	44	34	66	
Mean (StdDev)	40.87 (10.483)	40.47 (11.145)	32.64 (10.389)	37.67 (12.596)	
Median	36.27	46.54	36.27	36.27	
Min, Max	26.0, 56.8	15.7, 56.8	15.7, 56.8	15.7, 56.8	
C3D1 CFB					
n	27	43	33	65	
LS Mean (StdErr) [2]	6.07 (2.102)	8.07 (1.769)	1.71 (1.781)	7.13 (1.321)	
95% CI [2]	1.87, 10.27	4.54, 11.60	-1.83, 5.24	4.50, 9.75	
Difference (95% CI) in CFB [2]		2.00 (-2.64, 6.65)		5.42 (1.64, 9.20)	
p-value [3]		0.393		0.005	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	22	43	34	69	
Mean (StdDev)	40.94 (11.307)	40.33 (11.889)	32.95 (9.701)	37.16 (13.032)	
Median	36.27	46.54	36.27	36.27	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 46.5	15.7, 56.8	
C4D1 CFB					
n	20	42	33	67	
LS Mean (StdErr) [2]	3.91 (2.600)	4.52 (2.195)	1.16 (2.028)	5.96 (1.504)	
95% CI [2]	-1.30, 9.11	0.13, 8.91	-2.86, 5.19	2.97, 8.94	
Difference (95% CI) in CFB [2]		0.61 (-4.70, 5.93)		4.80 (0.51, 9.09)	
p-value [3]		0.818		0.029	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	26	41	34	68	
Mean (StdDev)	39.82 (12.643)	40.78 (13.001)	32.64 (11.274)	36.72 (13.092)	
Median	46.54	46.54	36.27	36.27	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 56.8	15.7, 56.8	
C5D1 CFB					
n	25	38	33	66	
LS Mean (StdErr) [2]	2.85 (2.209)	5.81 (1.872)	1.19 (2.177)	5.99 (1.627)	
95% CI [2]	-1.57, 7.27	2.06, 9.55	-3.14, 5.51	2.76, 9.22	
Difference (95% CI) in CFB [2]		2.96 (-1.96, 7.88)		4.80 (0.19, 9.42)	
p-value [3]		0.234		0.041	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	24	44	33	67	
Mean (StdDev)	37.98 (13.085)	42.10 (11.380)	32.84 (12.491)	37.80 (13.646)	
Median	36.27	46.54	36.27	36.27	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 56.8	15.7, 56.8	
C6D1 CFB					
n	23	41	32	65	
LS Mean (StdErr) [2]	2.78 (2.228)	8.48 (1.847)	0.40 (2.123)	6.38 (1.566)	
95% CI [2]	-1.68, 7.23	4.78, 12.17	-3.82, 4.61	3.27, 9.49	
Difference (95% CI) in CFB [2]		5.70 (0.75, 10.65)		5.98 (1.46, 10.50)	
p-value [3]		0.025		0.010	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	24	44	34	67	
Mean (StdDev)	40.55 (12.083)	42.34 (12.396)	35.06 (10.657)	36.88 (13.950)	
Median	41.40	46.54	36.27	36.27	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 56.8	15.7, 56.8	
C7D1 CFB					
n	23	41	33	65	
LS Mean (StdErr) [2]	1.73 (2.423)	6.10 (1.940)	1.76 (2.021)	4.15 (1.499)	
95% CI [2]	-3.12, 6.57	2.22, 9.98	-2.26, 5.77	1.17, 7.13	
Difference (95% CI) in CFB [2]		4.37 (-0.73, 9.47)		2.39 (-1.90, 6.69)	
Hedges'G (95% CI) in CFB		0.36 (-0.16, 0.89)		0.20 (-0.22, 0.63)	
p-value [3]		0.092		0.271	
					0.531

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	30	49	34	70	
Mean (StdDev)	36.14 (11.404)	35.25 (10.382)	32.11 (9.637)	31.99 (8.747)	
Median	30.05	30.05	30.05	30.05	
Min, Max	19.4, 61.9	19.4, 55.5	19.4, 55.5	19.4, 55.5	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	30	51	35	68	
Mean (StdDev)	38.40 (11.447)	37.46 (10.515)	34.17 (10.458)	33.36 (10.372)	
Median	30.05	30.05	30.05	30.05	
Min, Max	19.4, 55.5	19.4, 55.5	19.4, 55.5	19.4, 55.5	
C2D1 CFB					
n	28	48	34	68	
LS Mean (StdErr) [2]	1.08 (1.828)	2.28 (1.522)	2.16 (1.686)	1.51 (1.269)	
95% CI [2]	-2.56, 4.73	-0.75, 5.31	-1.19, 5.50	-1.01, 4.02	
Difference (95% CI) in CFB [2]		1.20 (-2.84, 5.23)		-0.65 (-4.23, 2.93)	
p-value [3]		0.556		0.719	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	29	44	34	66	
Mean (StdDev)	36.05 (10.174)	38.30 (11.466)	33.73 (9.997)	35.71 (10.745)	
Median	30.05	44.92	30.05	30.05	
Min, Max	19.4, 55.5	19.4, 55.5	19.4, 55.5	19.4, 61.9	
C3D1 CFB					
n	27	43	33	66	
LS Mean (StdErr) [2]	-1.28 (2.072)	3.83 (1.743)	0.93 (1.780)	3.23 (1.304)	
95% CI [2]	-5.41, 2.86	0.35, 7.31	-2.61, 4.46	0.64, 5.81	
Difference (95% CI) in CFB [2]		5.11 (0.53, 9.68)		2.30 (-1.48, 6.08)	
p-value [3]		0.029		0.230	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	22	44	34	69	
Mean (StdDev)	38.74 (12.106)	40.04 (10.323)	34.04 (9.698)	34.66 (10.943)	
Median	37.48	44.92	30.05	30.05	
Min, Max	19.4, 61.9	19.4, 55.5	19.4, 55.5	19.4, 55.5	
C4D1 CFB					
n	20	43	33	68	
LS Mean (StdErr) [2]	-0.29 (2.317)	3.55 (1.858)	1.55 (1.931)	2.32 (1.414)	
95% CI [2]	-4.92, 4.35	-0.17, 7.27	-2.28, 5.38	-0.49, 5.13	
Difference (95% CI) in CFB [2]		3.84 (-0.97, 8.64)		0.77 (-3.31, 4.85)	
p-value [3]		0.116		0.710	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	26	41	34	68	
Mean (StdDev)	37.97 (11.536)	39.89 (10.567)	34.48 (8.974)	35.73 (10.661)	
Median	30.05	44.92	30.05	30.05	
Min, Max	19.4, 61.9	19.4, 55.5	19.4, 44.9	19.4, 55.5	
C5D1 CFB					
n	25	38	33	67	
LS Mean (StdErr) [2]	1.41 (2.096)	4.83 (1.776)	1.83 (1.944)	3.24 (1.435)	
95% CI [2]	-2.79, 5.60	1.28, 8.38	-2.03, 5.69	0.39, 6.08	
Difference (95% CI) in CFB [2]		3.42 (-1.25, 8.09)		1.41 (-2.71, 5.53)	
p-value [3]		0.148		0.499	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	24	44	34	67	
Mean (StdDev)	38.37 (12.762)	42.31 (9.116)	34.17 (10.155)	35.37 (11.384)	
Median	44.92	44.92	30.05	30.05	
Min, Max	19.4, 61.9	19.4, 55.5	19.4, 55.5	19.4, 55.5	
C6D1 CFB					
n	23	41	33	66	
LS Mean (StdErr) [2]	0.96 (1.975)	7.40 (1.637)	1.64 (1.966)	3.16 (1.440)	
95% CI [2]	-2.99, 4.91	4.13, 10.68	-2.26, 5.54	0.30, 6.02	
Difference (95% CI) in CFB [2]		6.44 (2.05, 10.83)		1.52 (-2.66, 5.69)	
p-value [3]		0.005		0.472	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	24	44	34	67	
Mean (StdDev)	39.61 (12.132)	43.57 (8.683)	34.04 (9.698)	35.47 (11.401)	
Median	44.92	44.92	30.05	30.05	
Min, Max	19.4, 55.5	19.4, 55.5	19.4, 55.5	19.4, 55.5	
C7D1 CFB					
n	23	41	33	66	
LS Mean (StdErr) [2]	-0.64 (2.177)	6.98 (1.743)	1.26 (1.946)	2.68 (1.425)	
95% CI [2]	-4.99, 3.71	3.49, 10.47	-2.61, 5.12	-0.15, 5.51	
Difference (95% CI) in CFB [2]		7.62 (3.03, 12.21)		1.43 (-2.70, 5.56)	
Hedges'G (95% CI) in CFB		0.69 (0.18, 1.25)		0.12 (-0.30, 0.55)	
p-value [3]		0.002		0.494	
					0.054

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	30	49	34	70	
Mean (StdDev)	38.57 (9.406)	36.86 (7.711)	39.97 (8.813)	36.86 (8.514)	
Median	38.25	38.25	38.25	38.25	
Min, Max	28.5, 57.8	28.5, 48.0	28.5, 57.8	28.5, 57.8	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	30	51	35	68	
Mean (StdDev)	40.85 (8.470)	40.35 (10.007)	40.20 (9.696)	38.11 (9.152)	
Median	38.25	38.25	38.25	38.25	
Min, Max	28.5, 57.8	28.5, 57.8	28.5, 67.5	28.5, 57.8	
C2D1 CFB					
n	28	48	34	68	
LS Mean (StdErr) [2]	2.29 (1.840)	4.89 (1.531)	0.18 (1.453)	1.21 (1.093)	
95% CI [2]	-1.38, 5.96	1.83, 7.94	-2.70, 3.06	-0.96, 3.38	
Difference (95% CI) in CFB [2]		2.60 (-1.46, 6.66)		1.03 (-2.05, 4.12)	
p-value [3]		0.207		0.507	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	29	44	34	66	
Mean (StdDev)	39.93 (9.778)	40.69 (10.332)	42.84 (9.675)	39.87 (9.462)	
Median	38.25	38.25	38.25	38.25	
Min, Max	28.5, 57.8	28.5, 57.8	28.5, 67.5	28.5, 57.8	
C3D1 CFB					
n	27	43	33	66	
LS Mean (StdErr) [2]	1.80 (1.951)	5.53 (1.642)	3.54 (1.437)	2.89 (1.053)	
95% CI [2]	-2.10, 5.69	2.26, 8.81	0.69, 6.39	0.80, 4.98	
Difference (95% CI) in CFB [2]		3.74 (-0.58, 8.05)		-0.65 (-3.70, 2.40)	
p-value [3]		0.088		0.673	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	22	44	34	69	
Mean (StdDev)	38.25 (8.514)	40.91 (9.493)	41.40 (8.564)	40.09 (10.747)	
Median	38.25	38.25	38.25	38.25	
Min, Max	28.5, 48.0	28.5, 57.8	28.5, 57.8	28.5, 57.8	
C4D1 CFB					
n	20	43	33	68	
LS Mean (StdErr) [2]	1.62 (2.055)	4.06 (1.648)	1.53 (1.944)	2.81 (1.424)	
95% CI [2]	-2.49, 5.73	0.77, 7.36	-2.33, 5.39	-0.01, 5.64	
Difference (95% CI) in CFB [2]		2.44 (-1.82, 6.71)		1.29 (-2.83, 5.40)	
p-value [3]		0.256		0.536	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	26	41	34	68	
Mean (StdDev)	41.25 (9.053)	41.58 (8.889)	39.40 (9.534)	40.11 (10.692)	
Median	38.25	38.25	38.25	38.25	
Min, Max	28.5, 57.8	28.5, 57.8	28.5, 57.8	28.5, 67.5	
C5D1 CFB					
n	25	38	33	67	
LS Mean (StdErr) [2]	3.78 (2.048)	6.18 (1.735)	-0.89 (1.894)	2.73 (1.398)	
95% CI [2]	-0.32, 7.88	2.70, 9.65	-4.65, 2.87	-0.05, 5.50	
Difference (95% CI) in CFB [2]		2.40 (-2.17, 6.96)		3.61 (-0.40, 7.63)	
p-value [3]		0.297		0.077	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	24	44	34	67	
Mean (StdDev)	39.06 (9.058)	42.90 (10.410)	38.82 (8.966)	41.31 (10.217)	
Median	38.25	38.25	38.25	38.25	
Min, Max	28.5, 57.8	28.5, 57.8	28.5, 57.8	28.5, 67.5	
C6D1 CFB					
n	23	41	33	66	
LS Mean (StdErr) [2]	1.02 (1.953)	6.06 (1.619)	-0.33 (1.814)	4.43 (1.329)	
95% CI [2]	-2.89, 4.92	2.82, 9.30	-3.94, 3.27	1.79, 7.07	
Difference (95% CI) in CFB [2]		5.04 (0.70, 9.38)		4.76 (0.91, 8.62)	
p-value [3]		0.024		0.016	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	24	44	34	67	
Mean (StdDev)	41.09 (10.560)	43.13 (10.623)	41.40 (10.663)	40.14 (10.221)	
Median	38.25	43.13	38.25	38.25	
Min, Max	28.5, 57.8	28.5, 57.8	28.5, 67.5	28.5, 67.5	
C7D1 CFB					
n	23	41	33	66	
LS Mean (StdErr) [2]	3.97 (2.235)	6.54 (1.789)	1.31 (1.726)	2.58 (1.265)	
95% CI [2]	-0.50, 8.44	2.96, 10.12	-2.12, 4.74	0.07, 5.09	
Difference (95% CI) in CFB [2]		2.57 (-2.14, 7.28)		1.27 (-2.40, 4.94)	
Hedges'G (95% CI) in CFB		0.23 (-0.29, 0.76)		0.12 (-0.30, 0.55)	
p-value [3]		0.279		0.493	
					0.604

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	30	49	34	70	
Mean (StdDev)	38.93 (12.468)	37.70 (10.898)	34.83 (10.951)	36.00 (10.537)	
Median	36.29	36.29	36.29	36.29	
Min, Max	16.5, 56.1	16.5, 56.1	16.5, 56.1	16.5, 56.1	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	30	51	35	68	
Mean (StdDev)	42.23 (10.608)	42.31 (11.575)	37.70 (10.242)	38.76 (11.150)	
Median	46.20	46.20	36.29	36.29	
Min, Max	16.5, 56.1	16.5, 56.1	16.5, 56.1	16.5, 56.1	
C2D1 CFB					
n	28	48	34	68	
LS Mean (StdErr) [2]	1.63 (2.058)	4.07 (1.713)	3.00 (1.971)	2.69 (1.484)	
95% CI [2]	-2.47, 5.73	0.66, 7.49	-0.91, 6.92	-0.25, 5.64	
Difference (95% CI) in CFB [2]		2.44 (-2.10, 6.99)		-0.31 (-4.50, 3.87)	
p-value [3]		0.287		0.883	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	29	44	34	66	
Mean (StdDev)	42.78 (11.633)	42.14 (11.577)	39.20 (10.786)	38.99 (11.864)	
Median	46.20	46.20	36.29	36.29	
Min, Max	16.5, 56.1	16.5, 56.1	16.5, 56.1	16.5, 56.1	
C3D1 CFB					
n	27	43	33	66	
LS Mean (StdErr) [2]	4.00 (2.043)	4.70 (1.719)	4.53 (1.953)	3.03 (1.431)	
95% CI [2]	-0.08, 8.07	1.27, 8.13	0.66, 8.41	0.19, 5.87	
Difference (95% CI) in CFB [2]		0.70 (-3.81, 5.22)		-1.51 (-5.66, 2.64)	
p-value [3]		0.757		0.473	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	22	44	34	69	
Mean (StdDev)	41.69 (12.133)	41.92 (10.775)	38.04 (10.201)	39.45 (13.333)	
Median	46.20	46.20	36.29	36.29	
Min, Max	16.5, 56.1	16.5, 56.1	16.5, 56.1	16.5, 56.1	
C4D1 CFB					
n	20	43	33	68	
LS Mean (StdErr) [2]	1.01 (2.526)	3.93 (2.025)	3.51 (2.207)	3.68 (1.616)	
95% CI [2]	-4.04, 6.07	-0.13, 7.98	-0.87, 7.89	0.47, 6.88	
Difference (95% CI) in CFB [2]		2.91 (-2.32, 8.15)		0.16 (-4.51, 4.83)	
p-value [3]		0.270		0.945	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	26	41	34	68	
Mean (StdDev)	43.91 (12.321)	44.27 (11.776)	35.99 (10.206)	41.24 (12.411)	
Median	46.20	46.20	36.29	41.24	
Min, Max	16.5, 56.1	16.5, 56.1	16.5, 56.1	16.5, 56.1	
C5D1 CFB					
n	25	38	33	67	
LS Mean (StdErr) [2]	5.08 (2.439)	8.31 (2.066)	0.14 (2.237)	4.45 (1.651)	
95% CI [2]	0.20, 9.96	4.18, 12.45	-4.30, 4.58	1.17, 7.73	
Difference (95% CI) in CFB [2]		3.23 (-2.20, 8.67)		4.31 (-0.43, 9.05)	
p-value [3]		0.239		0.074	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-reg-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	24	44	34	67	
Mean (StdDev)	41.24 (12.403)	45.75 (10.018)	37.45 (10.851)	39.25 (12.801)	
Median	46.20	46.20	36.29	36.29	
Min, Max	16.5, 56.1	16.5, 56.1	16.5, 56.1	16.5, 56.1	
C6D1 CFB					
n	23	41	33	66	
LS Mean (StdErr) [2]	0.59 (2.610)	7.43 (2.164)	3.14 (2.235)	3.41 (1.637)	
95% CI [2]	-4.64, 5.81	3.10, 11.75	-1.30, 7.57	0.16, 6.66	
Difference (95% CI) in CFB [2]		6.84 (1.04, 12.64)		0.27 (-4.48, 5.02)	
p-value [3]		0.022		0.910	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	24	44	34	67	
Mean (StdDev)	45.37 (10.906)	45.52 (11.788)	36.58 (11.313)	40.73 (12.832)	
Median	46.20	46.20	36.29	46.20	
Min, Max	26.4, 56.1	16.5, 56.1	16.5, 56.1	16.5, 56.1	
C7D1 CFB					
n	23	41	33	66	
LS Mean (StdErr) [2]	1.95 (2.533)	6.52 (2.028)	1.59 (2.281)	4.09 (1.671)	
95% CI [2]	-3.12, 7.02	2.47, 10.58	-2.94, 6.12	0.77, 7.41	
Difference (95% CI) in CFB [2]		4.57 (-0.76, 9.91)		2.50 (-2.34, 7.35)	
Hedges'G (95% CI) in CFB		0.36 (-0.16, 0.89)		0.19 (-0.23, 0.61)	
p-value [3]		0.092		0.307	
					0.587

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-reg-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	30	49	34	70	
Mean (StdDev)	41.85 (11.295)	38.26 (10.608)	33.27 (11.152)	37.14 (12.476)	
Median	39.27	39.27	33.75	33.75	
Min, Max	22.7, 55.8	17.2, 55.8	11.7, 55.8	11.7, 55.8	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-reg-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	30	51	35	68	
Mean (StdDev)	43.87 (11.234)	42.30 (10.195)	36.59 (10.656)	39.76 (13.065)	
Median	47.55	44.79	39.27	39.27	
Min, Max	22.7, 55.8	17.2, 55.8	17.2, 55.8	11.7, 55.8	
C2D1 CFB					
n	28	48	34	68	
LS Mean (StdErr) [2]	2.45 (1.823)	4.25 (1.518)	3.50 (1.903)	2.93 (1.432)	
95% CI [2]	-1.19, 6.08	1.23, 7.28	-0.27, 7.28	0.08, 5.77	
Difference (95% CI) in CFB [2]		1.81 (-2.22, 5.83)		-0.58 (-4.61, 3.46)	
p-value [3]		0.374		0.778	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	29	44	34	66	
Mean (StdDev)	46.12 (11.488)	41.28 (12.934)	35.86 (11.450)	41.36 (11.608)	
Median	50.31	44.79	33.75	44.79	
Min, Max	11.7, 55.8	11.7, 55.8	11.7, 55.8	11.7, 55.8	
C3D1 CFB					
n	27	43	33	66	
LS Mean (StdErr) [2]	4.36 (2.279)	3.79 (1.918)	2.85 (1.849)	4.68 (1.354)	
95% CI [2]	-0.19, 8.91	-0.03, 7.62	-0.82, 6.52	1.99, 7.37	
Difference (95% CI) in CFB [2]		-0.56 (-5.60, 4.47)		1.83 (-2.10, 5.75)	
p-value [3]		0.824		0.358	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	22	43	34	69	
Mean (StdDev)	45.54 (10.945)	44.02 (11.141)	35.05 (11.291)	41.03 (12.751)	
Median	44.79	44.79	33.75	44.79	
Min, Max	22.7, 55.8	17.2, 55.8	17.2, 55.8	11.7, 55.8	
C4D1 CFB					
n	20	42	33	68	
LS Mean (StdErr) [2]	4.73 (2.690)	5.64 (2.160)	2.02 (2.095)	4.29 (1.534)	
95% CI [2]	-0.66, 10.12	1.31, 9.96	-2.14, 6.18	1.24, 7.33	
Difference (95% CI) in CFB [2]		0.91 (-4.69, 6.50)		2.27 (-2.16, 6.70)	
p-value [3]		0.747		0.312	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	26	41	34	68	
Mean (StdDev)	46.06 (11.397)	44.12 (10.413)	36.35 (11.387)	41.71 (11.809)	
Median	50.31	44.79	33.75	44.79	
Min, Max	17.2, 55.8	22.7, 55.8	11.7, 55.8	11.7, 55.8	
C5D1 CFB					
n	25	38	33	67	
LS Mean (StdErr) [2]	3.57 (2.331)	5.30 (1.975)	2.53 (2.278)	4.53 (1.681)	
95% CI [2]	-1.10, 8.23	1.34, 9.25	-1.99, 7.05	1.19, 7.86	
Difference (95% CI) in CFB [2]		1.73 (-3.46, 6.92)		2.00 (-2.83, 6.83)	
p-value [3]		0.508		0.413	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	24	44	34	67	
Mean (StdDev)	47.78 (10.669)	45.29 (10.016)	35.38 (12.117)	39.02 (12.797)	
Median	55.83	44.79	33.75	44.79	
Min, Max	22.7, 55.8	22.7, 55.8	11.7, 55.8	11.7, 55.8	
C6D1 CFB					
n	23	41	33	66	
LS Mean (StdErr) [2]	4.60 (2.493)	5.24 (2.067)	0.90 (2.377)	1.59 (1.741)	
95% CI [2]	-0.39, 9.59	1.11, 9.37	-3.82, 5.62	-1.86, 5.05	
Difference (95% CI) in CFB [2]		0.64 (-4.90, 6.18)		0.69 (-4.36, 5.74)	
p-value [3]		0.819		0.786	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	24	44	34	67	
Mean (StdDev)	45.94 (10.161)	43.91 (9.811)	35.38 (12.784)	41.08 (12.868)	
Median	47.55	44.79	33.75	44.79	
Min, Max	28.2, 55.8	17.2, 55.8	11.7, 55.8	11.7, 55.8	
C7D1 CFB					
n	23	41	33	66	
LS Mean (StdErr) [2]	-0.28 (2.019)	4.32 (1.617)	0.81 (2.129)	3.08 (1.559)	
95% CI [2]	-4.32, 3.76	1.09, 7.55	-3.42, 5.03	-0.01, 6.18	
Difference (95% CI) in CFB [2]		4.60 (0.35, 8.85)		2.28 (-2.24, 6.80)	
Hedges'G (95% CI) in CFB		0.45 (-0.06, 0.99)		0.18 (-0.24, 0.61)	
p-value [3]		0.034		0.320	
					0.498

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-reg-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	30	49	34	70	
Mean (StdDev)	44.26 (9.543)	38.23 (9.640)	38.16 (8.611)	39.85 (9.849)	
Median	45.68	39.59	33.51	39.59	
Min, Max	27.4, 57.8	15.3, 57.8	21.3, 57.8	21.3, 63.9	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-reg-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	30	51	35	68	
Mean (StdDev)	43.24 (10.669)	40.19 (11.034)	40.46 (10.022)	41.65 (9.837)	
Median	45.68	39.59	39.59	39.59	
Min, Max	21.3, 57.8	15.3, 57.8	27.4, 57.8	15.3, 57.8	
C2D1 CFB					
n	28	48	34	68	
LS Mean (StdErr) [2]	-0.11 (1.485)	3.30 (1.237)	1.91 (1.390)	1.64 (1.046)	
95% CI [2]	-3.07, 2.85	0.84, 5.77	-0.85, 4.67	-0.43, 3.72	
Difference (95% CI) in CFB [2]		3.41 (0.13, 6.69)		-0.27 (-3.22, 2.68)	
p-value [3]		0.042		0.857	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	29	44	34	66	
Mean (StdDev)	46.10 (9.330)	42.22 (11.467)	39.06 (9.862)	43.93 (10.764)	
Median	45.68	45.68	39.59	45.68	
Min, Max	27.4, 57.8	21.3, 57.8	15.3, 63.9	15.3, 63.9	
C3D1 CFB					
n	27	43	33	66	
LS Mean (StdErr) [2]	1.85 (1.606)	5.13 (1.352)	0.73 (1.809)	3.96 (1.325)	
95% CI [2]	-1.36, 5.06	2.43, 7.83	-2.86, 4.32	1.33, 6.59	
Difference (95% CI) in CFB [2]		3.28 (-0.27, 6.83)		3.23 (-0.62, 7.07)	
p-value [3]		0.069		0.099	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	22	44	34	69	
Mean (StdDev)	45.40 (9.288)	45.12 (10.562)	39.95 (9.464)	42.86 (11.118)	
Median	45.68	45.68	39.59	45.68	
Min, Max	27.4, 57.8	27.4, 63.9	21.3, 63.9	15.3, 63.9	
C4D1 CFB					
n	20	43	33	68	
LS Mean (StdErr) [2]	2.66 (2.121)	8.18 (1.700)	2.17 (1.715)	3.40 (1.256)	
95% CI [2]	-1.58, 6.90	4.78, 11.58	-1.24, 5.57	0.91, 5.89	
Difference (95% CI) in CFB [2]		5.52 (1.12, 9.92)		1.23 (-2.39, 4.86)	
p-value [3]		0.015		0.502	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	26	41	34	68	
Mean (StdDev)	47.08 (9.930)	43.30 (10.259)	38.70 (10.172)	43.35 (10.720)	
Median	45.68	45.68	39.59	45.68	
Min, Max	27.4, 63.9	15.3, 57.8	21.3, 63.9	21.3, 63.9	
C5D1 CFB					
n	25	38	33	67	
LS Mean (StdErr) [2]	2.46 (1.899)	5.11 (1.609)	0.89 (1.884)	4.31 (1.390)	
95% CI [2]	-1.34, 6.26	1.89, 8.33	-2.84, 4.63	1.55, 7.07	
Difference (95% CI) in CFB [2]		2.65 (-1.59, 6.88)		3.41 (-0.58, 7.40)	
p-value [3]		0.216		0.093	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	24	44	33	67	
Mean (StdDev)	45.93 (10.982)	44.29 (10.151)	40.33 (8.836)	41.68 (11.184)	
Median	48.72	45.68	39.59	45.68	
Min, Max	27.4, 63.9	15.3, 57.8	27.4, 63.9	15.3, 63.9	
C6D1 CFB					
n	23	41	32	66	
LS Mean (StdErr) [2]	0.69 (1.769)	6.42 (1.467)	2.17 (1.926)	2.68 (1.403)	
95% CI [2]	-2.85, 4.22	3.48, 9.35	-1.66, 5.99	-0.11, 5.46	
Difference (95% CI) in CFB [2]		5.73 (1.80, 9.66)		0.51 (-3.59, 4.61)	
p-value [3]		0.005		0.805	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	24	44	34	67	
Mean (StdDev)	45.68 (11.058)	45.68 (10.658)	39.95 (9.927)	42.23 (12.584)	
Median	45.68	45.68	39.59	39.59	
Min, Max	21.3, 63.9	21.3, 63.9	15.3, 63.9	15.3, 63.9	
C7D1 CFB					
n	23	41	33	66	
LS Mean (StdErr) [2]	0.28 (2.088)	7.26 (1.672)	2.39 (2.182)	3.03 (1.599)	
95% CI [2]	-3.90, 4.46	3.91, 10.60	-1.94, 6.72	-0.15, 6.20	
Difference (95% CI) in CFB [2]		6.98 (2.58, 11.38)		0.63 (-4.00, 5.27)	
Hedges'G (95% CI) in CFB		0.66 (0.15, 1.22)		0.05 (-0.37, 0.47)	
p-value [3]		0.002		0.787	
					0.064

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	30	49	34	69	
Mean (StdDev)	35.39 (11.499)	35.87 (11.591)	33.30 (10.419)	31.24 (9.434)	
Median	33.61	37.54	33.50	30.42	
Min, Max	13.8, 59.0	15.1, 61.8	14.0, 60.4	10.5, 54.1	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	30	51	35	68	
Mean (StdDev)	38.01 (11.693)	40.11 (12.269)	35.23 (10.634)	34.70 (11.499)	
Median	35.34	41.22	36.78	35.26	
Min, Max	16.5, 61.2	16.6, 58.5	16.9, 60.0	13.0, 52.2	
C2D1 CFB					
n	28	48	34	67	
LS Mean (StdErr) [2]	0.89 (1.494)	2.83 (1.243)	0.98 (1.337)	2.21 (1.020)	
95% CI [2]	-2.09, 3.87	0.36, 5.31	-1.67, 3.64	0.19, 4.23	
Difference (95% CI) in CFB [2]		1.95 (-1.35, 5.24)		1.23 (-1.61, 4.07)	
p-value [3]		0.244		0.392	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	29	44	34	66	
Mean (StdDev)	36.87 (10.494)	40.31 (11.922)	35.05 (10.220)	36.45 (11.923)	
Median	36.15	42.04	35.01	35.65	
Min, Max	15.1, 62.6	19.4, 58.0	17.4, 60.0	13.3, 61.4	
C3D1 CFB					
n	27	43	33	65	
LS Mean (StdErr) [2]	1.39 (1.552)	4.87 (1.306)	0.64 (1.309)	3.90 (0.971)	
95% CI [2]	-1.71, 4.49	2.26, 7.48	-1.96, 3.24	1.97, 5.83	
Difference (95% CI) in CFB [2]		3.48 (0.05, 6.91)		3.26 (0.48, 6.04)	
p-value [3]		0.047		0.022	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	22	42	34	68	
Mean (StdDev)	38.05 (12.673)	41.54 (11.417)	35.26 (9.488)	36.28 (11.353)	
Median	37.17	43.76	35.53	36.66	
Min, Max	10.8, 61.5	16.2, 59.8	19.8, 57.9	12.8, 58.5	
C4D1 CFB					
n	20	41	33	66	
LS Mean (StdErr) [2]	2.44 (1.806)	4.87 (1.526)	0.60 (1.503)	3.55 (1.130)	
95% CI [2]	-1.17, 6.06	1.81, 7.92	-2.38, 3.59	1.31, 5.79	
Difference (95% CI) in CFB [2]		2.42 (-1.28, 6.13)		2.95 (-0.23, 6.13)	
p-value [3]		0.196		0.069	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	26	41	34	68	
Mean (StdDev)	37.09 (13.135)	40.67 (11.549)	35.64 (9.908)	36.30 (12.409)	
Median	40.40	38.58	36.02	38.31	
Min, Max	13.5, 60.1	17.8, 62.4	18.5, 52.9	13.0, 64.3	
C5D1 CFB					
n	25	38	33	66	
LS Mean (StdErr) [2]	1.87 (1.385)	6.28 (1.174)	0.63 (1.542)	3.20 (1.152)	
95% CI [2]	-0.90, 4.64	3.93, 8.63	-2.43, 3.70	0.91, 5.49	
Difference (95% CI) in CFB [2]		4.41 (1.32, 7.49)		2.56 (-0.70, 5.83)	
p-value [3]		0.006		0.123	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	24	44	33	67	
Mean (StdDev)	36.01 (11.755)	43.43 (10.487)	34.69 (10.939)	37.83 (12.578)	
Median	33.45	46.05	34.04	37.33	
Min, Max	16.9, 58.8	17.5, 61.0	16.4, 58.5	17.3, 59.1	
C6D1 CFB					
n	23	41	32	65	
LS Mean (StdErr) [2]	0.89 (1.665)	8.15 (1.381)	-0.18 (1.528)	4.82 (1.127)	
95% CI [2]	-2.44, 4.22	5.39, 10.92	-3.22, 2.85	2.58, 7.06	
Difference (95% CI) in CFB [2]		7.26 (3.56, 10.96)		5.00 (1.75, 8.26)	
p-value [3]		<0.001		0.003	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-reg-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	24	44	34	67	
Mean (StdDev)	39.34 (12.318)	43.40 (11.108)	35.79 (10.279)	36.81 (12.341)	
Median	40.39	41.52	35.84	36.15	
Min, Max	19.0, 58.2	17.8, 63.1	14.5, 63.2	12.5, 60.6	
C7D1 CFB					
n	23	41	33	65	
LS Mean (StdErr) [2]	1.66 (1.827)	6.46 (1.463)	0.51 (1.507)	3.23 (1.118)	
95% CI [2]	-2.00, 5.31	3.54, 9.39	-2.48, 3.50	1.01, 5.45	
Difference (95% CI) in CFB [2]		4.81 (0.96, 8.65)		2.73 (-0.48, 5.93)	
Hedges'G (95% CI) in CFB		0.52 (0.01, 1.07)		0.30 (-0.12, 0.74)	
p-value [3]		0.015		0.094	
					0.374

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-reg-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
Baseline					
n	30	49	34	69	
Mean (StdDev)	43.63 (10.405)	39.04 (9.557)	37.94 (10.001)	40.56 (10.414)	
Median	42.14	38.10	35.93	41.43	
Min, Max	23.2, 58.7	19.7, 61.0	19.2, 58.6	13.2, 61.2	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-reg-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C2D1					
n	30	51	35	68	
Mean (StdDev)	44.61 (10.532)	41.80 (10.645)	40.23 (10.960)	41.88 (10.398)	
Median	45.04	41.67	40.01	41.70	
Min, Max	19.9, 60.7	19.6, 64.8	20.8, 64.4	19.0, 62.5	
C2D1 CFB					
n	28	48	34	67	
LS Mean (StdErr) [2]	1.58 (1.514)	4.08 (1.260)	2.46 (1.607)	1.80 (1.225)	
95% CI [2]	-1.44, 4.60	1.57, 6.60	-0.73, 5.65	-0.63, 4.23	
Difference (95% CI) in CFB [2]		2.50 (-0.84, 5.84)		-0.66 (-4.07, 2.75)	
p-value [3]		0.140		0.701	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C3D1					
n	29	44	34	66	
Mean (StdDev)	46.91 (10.665)	42.31 (11.362)	40.49 (10.536)	43.37 (9.960)	
Median	49.03	43.55	40.45	45.36	
Min, Max	22.9, 60.6	17.7, 60.6	11.2, 63.3	13.8, 66.0	
C3D1 CFB					
n	27	43	33	65	
LS Mean (StdErr) [2]	3.31 (1.751)	4.39 (1.474)	3.13 (1.629)	3.47 (1.208)	
95% CI [2]	-0.18, 6.81	1.45, 7.33	-0.10, 6.37	1.07, 5.87	
Difference (95% CI) in CFB [2]		1.08 (-2.79, 4.95)		0.34 (-3.12, 3.80)	
p-value [3]		0.580		0.848	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C4D1					
n	22	42	34	68	
Mean (StdDev)	45.46 (9.305)	44.29 (10.568)	39.83 (10.148)	43.34 (11.323)	
Median	44.51	45.81	39.47	43.70	
Min, Max	24.2, 58.4	24.3, 60.6	22.0, 59.7	13.7, 63.9	
C4D1 CFB					
n	20	41	33	66	
LS Mean (StdErr) [2]	2.24 (2.144)	5.26 (1.811)	2.89 (1.873)	3.77 (1.408)	
95% CI [2]	-2.06, 6.53	1.63, 8.88	-0.82, 6.61	0.97, 6.56	
Difference (95% CI) in CFB [2]		3.02 (-1.38, 7.42)		0.87 (-3.09, 4.84)	
p-value [3]		0.175		0.662	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C5D1					
n	26	41	34	68	
Mean (StdDev)	47.85 (10.322)	44.54 (10.849)	38.63 (11.335)	43.91 (10.826)	
Median	49.28	45.71	38.06	44.97	
Min, Max	27.1, 61.5	22.4, 62.4	14.1, 61.6	19.5, 64.4	
C5D1 CFB					
n	25	38	33	66	
LS Mean (StdErr) [2]	3.90 (1.978)	5.37 (1.676)	0.94 (2.070)	4.21 (1.546)	
95% CI [2]	-0.06, 7.85	2.01, 8.72	-3.17, 5.05	1.14, 7.28	
Difference (95% CI) in CFB [2]		1.47 (-2.94, 5.88)		3.27 (-1.12, 7.65)	
p-value [3]		0.507		0.143	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-reg-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C6D1					
n	24	44	33	67	
Mean (StdDev)	47.22 (10.564)	45.12 (10.345)	39.95 (9.918)	41.43 (11.433)	
Median	49.56	45.74	39.14	40.43	
Min, Max	28.3, 61.2	16.6, 61.5	24.1, 61.4	12.1, 61.4	
C6D1 CFB					
n	23	41	32	65	
LS Mean (StdErr) [2]	2.11 (1.957)	5.14 (1.622)	2.27 (2.051)	1.79 (1.513)	
95% CI [2]	-1.81, 6.02	1.90, 8.39	-1.80, 6.34	-1.21, 4.79	
Difference (95% CI) in CFB [2]		3.04 (-1.31, 7.39)		-0.48 (-4.85, 3.89)	
p-value [3]		0.168		0.827	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.3a
Change from Baseline of SF-12 by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Region = North America		Region = Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	Test of Interaction p-value [1]
C7D1					
n	24	44	34	67	
Mean (StdDev)	46.88 (9.479)	45.32 (10.613)	39.46 (11.943)	42.91 (12.128)	
Median	48.04	44.55	40.77	44.27	
Min, Max	32.5, 64.6	19.6, 62.0	12.1, 64.9	12.0, 63.3	
C7D1 CFB					
n	23	41	33	65	
LS Mean (StdErr) [2]	0.91 (1.937)	5.71 (1.551)	1.93 (2.035)	3.00 (1.510)	
95% CI [2]	-2.97, 4.78	2.61, 8.82	-2.11, 5.97	0.00, 6.00	
Difference (95% CI) in CFB [2]		4.81 (0.73, 8.89)		1.07 (-3.25, 5.40)	
Hedges'G (95% CI) in CFB		0.49 (-0.02, 1.03)		0.09 (-0.33, 0.52)	
p-value [3]		0.022		0.623	
					0.246

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.4a
Change from Baseline of SF-12 by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.4a
Change from Baseline of SF-12 by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score						
	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.4a
Change from Baseline of SF-12 by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-cou-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.4a
Change from Baseline of SF-12 by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-cou-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.4a
Change from Baseline of SF-12 by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score			
	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-cou-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.4a
Change from Baseline of SF-12 by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.4a
Change from Baseline of SF-12 by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.4a
Change from Baseline of SF-12 by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.10.2.4a
Change from Baseline of SF-12 by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.4a
Change from Baseline of SF-12 by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.4a
Change from Baseline of SF-12 by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.4a
Change from Baseline of SF-12 by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score						
	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.10.2.4a
Change from Baseline of SF-12 by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.4a
Change from Baseline of SF-12 by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.4a
Change from Baseline of SF-12 by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score

	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.4a
Change from Baseline of SF-12 by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.10.2.4a
Change from Baseline of SF-12 by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.4a
Change from Baseline of SF-12 by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.10.2.4a
Change from Baseline of SF-12 by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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Table 35.2.10.2.4a
Change from Baseline of SF-12 by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score			
	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.4a
Change from Baseline of SF-12 by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.4a
Change from Baseline of SF-12 by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score						
	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
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[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.4a
Change from Baseline of SF-12 by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
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[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-cou-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.4a
Change from Baseline of SF-12 by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.4a
Change from Baseline of SF-12 by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score			
	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.4a
Change from Baseline of SF-12 by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.4a
Change from Baseline of SF-12 by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score						
	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.4a
Change from Baseline of SF-12 by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.4a
Change from Baseline of SF-12 by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.4a
Change from Baseline of SF-12 by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score			
	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.4a
Change from Baseline of SF-12 by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.4a
Change from Baseline of SF-12 by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.4a
Change from Baseline of SF-12 by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.4a
Change from Baseline of SF-12 by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.4a
Change from Baseline of SF-12 by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score			
	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.4a
Change from Baseline of SF-12 by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.4a
Change from Baseline of SF-12 by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score						
	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.4a
Change from Baseline of SF-12 by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.4a
Change from Baseline of SF-12 by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.4a
Change from Baseline of SF-12 by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score			
	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.4a
Change from Baseline of SF-12 by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-cou-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.4a
Change from Baseline of SF-12 by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-cou-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.4a
Change from Baseline of SF-12 by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-cou-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.4a
Change from Baseline of SF-12 by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-cou-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.4a
Change from Baseline of SF-12 by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-cou-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.4a
Change from Baseline of SF-12 by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-cou-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.4a
Change from Baseline of SF-12 by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=14)	Avapritinib 25 mg (N=17)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=13)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-cou-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.4a
Change from Baseline of SF-12 by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=0)	Avapritinib 25 mg (N=3)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.4a
Change from Baseline of SF-12 by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=1)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.4a
Change from Baseline of SF-12 by Country
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Country = USA		
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-cou-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	20	35	44	84	
Mean (StdDev)	41.79 (11.214)	43.05 (12.278)	36.43 (12.469)	34.08 (9.803)	
Median	39.69	48.10	31.27	31.27	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-ism-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	21	35	44	84	
Mean (StdDev)	42.89 (10.800)	44.73 (11.215)	38.54 (10.977)	37.88 (11.687)	
Median	39.69	48.10	39.69	39.69	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C2D1 CFB					
n	19	34	43	82	
LS Mean (StdErr) [2]	0.24 (2.061)	1.14 (1.333)	2.40 (1.252)	3.36 (1.012)	
95% CI [2]	-3.90, 4.38	-1.54, 3.82	-0.08, 4.88	1.36, 5.36	
Difference (95% CI) in CFB [2]		0.90 (-3.29, 5.09)		0.96 (-1.94, 3.85)	
p-value [3]		0.667		0.514	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	18	33	45	77	
Mean (StdDev)	40.15 (10.192)	46.06 (11.137)	38.56 (10.398)	37.94 (11.689)	
Median	39.69	48.10	39.69	39.69	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C3D1 CFB					
n	16	33	44	76	
LS Mean (StdErr) [2]	-1.17 (2.087)	2.51 (1.286)	1.97 (1.269)	4.05 (1.050)	
95% CI [2]	-5.37, 3.03	-0.08, 5.10	-0.54, 4.49	1.97, 6.13	
Difference (95% CI) in CFB [2]		3.68 (-0.59, 7.95)		2.08 (-0.89, 5.05)	
p-value [3]		0.090		0.169	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	17	33	39	80	
Mean (StdDev)	41.17 (10.822)	45.80 (10.363)	38.39 (10.840)	38.53 (11.340)	
Median	39.69	48.10	39.69	39.69	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C4D1 CFB					
n	15	32	38	79	
LS Mean (StdErr) [2]	0.89 (2.804)	3.92 (1.788)	3.25 (1.419)	4.87 (1.091)	
95% CI [2]	-4.76, 6.54	0.31, 7.52	0.44, 6.07	2.71, 7.03	
Difference (95% CI) in CFB [2]		3.03 (-2.48, 8.53)		1.61 (-1.60, 4.83)	
p-value [3]		0.273		0.322	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	32	41	77	
Mean (StdDev)	42.34 (11.917)	45.73 (11.153)	38.66 (12.365)	38.81 (11.386)	
Median	39.69	48.10	39.69	39.69	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C5D1 CFB					
n	17	30	41	75	
LS Mean (StdErr) [2]	-0.86 (2.768)	2.96 (1.794)	2.66 (1.375)	5.72 (1.091)	
95% CI [2]	-6.44, 4.72	-0.65, 6.58	-0.06, 5.39	3.55, 7.88	
Difference (95% CI) in CFB [2]		3.82 (-1.83, 9.48)		3.05 (-0.13, 6.24)	
p-value [3]		0.180		0.060	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	19	33	39	78	
Mean (StdDev)	41.01 (11.311)	47.08 (11.082)	37.53 (11.209)	40.01 (12.162)	
Median	39.69	48.10	39.69	39.69	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C6D1 CFB					
n	17	31	39	76	
LS Mean (StdErr) [2]	-1.66 (2.584)	4.32 (1.669)	1.29 (1.437)	5.53 (1.119)	
95% CI [2]	-6.86, 3.54	0.96, 7.68	-1.56, 4.13	3.31, 7.74	
Difference (95% CI) in CFB [2]		5.98 (0.74, 11.22)		4.24 (0.92, 7.56)	
p-value [3]		0.026		0.013	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-ism-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	18	35	40	76	
Mean (StdDev)	40.15 (12.735)	45.21 (11.352)	39.05 (10.675)	39.91 (12.133)	
Median	39.69	48.10	39.69	39.69	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C7D1 CFB					
n	16	33	40	74	
LS Mean (StdErr) [2]	-3.62 (3.123)	0.99 (1.969)	2.12 (1.446)	5.93 (1.145)	
95% CI [2]	-9.90, 2.67	-2.97, 4.95	-0.75, 4.98	3.66, 8.20	
Difference (95% CI) in CFB [2]		4.61 (-1.64, 10.85)		3.81 (0.51, 7.11)	
Hedges'G (95% CI) in CFB		0.39 (-0.21, 1.02)		0.39 (0.01, 0.79)	
p-value [3]		0.145		0.024	
					0.981

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-ism-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	20	35	44	84	
Mean (StdDev)	35.41 (9.049)	38.36 (8.514)	34.31 (7.307)	32.43 (7.898)	
Median	34.51	39.00	32.27	30.03	
Min, Max	21.0, 52.5	21.0, 57.0	21.0, 48.0	21.0, 48.0	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	21	35	44	84	
Mean (StdDev)	38.58 (10.228)	40.16 (9.637)	35.23 (9.131)	35.37 (9.965)	
Median	39.00	39.00	34.51	34.51	
Min, Max	21.0, 57.0	25.5, 57.0	21.0, 57.0	21.0, 57.0	
C2D1 CFB					
n	19	34	43	82	
LS Mean (StdErr) [2]	1.95 (1.791)	1.10 (1.158)	0.39 (1.229)	2.33 (0.994)	
95% CI [2]	-1.65, 5.55	-1.23, 3.42	-2.04, 2.82	0.36, 4.30	
Difference (95% CI) in CFB [2]		-0.85 (-4.49, 2.79)		1.94 (-0.91, 4.78)	
p-value [3]		0.641		0.180	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	18	33	45	77	
Mean (StdDev)	38.26 (9.271)	42.41 (8.696)	36.01 (10.038)	36.96 (10.542)	
Median	39.00	39.00	34.51	39.00	
Min, Max	25.5, 57.0	21.0, 57.0	21.0, 57.0	21.0, 57.0	
C3D1 CFB					
n	16	33	44	76	
LS Mean (StdErr) [2]	-0.31 (2.281)	2.40 (1.405)	1.69 (1.209)	5.15 (1.000)	
95% CI [2]	-4.90, 4.28	-0.43, 5.23	-0.71, 4.08	3.17, 7.13	
Difference (95% CI) in CFB [2]		2.71 (-1.96, 7.38)		3.46 (0.63, 6.29)	
p-value [3]		0.248		0.017	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	17	33	39	78	
Mean (StdDev)	37.42 (10.521)	41.86 (8.895)	36.01 (9.950)	38.43 (10.789)	
Median	39.00	43.49	34.51	39.00	
Min, Max	21.0, 57.0	30.0, 57.0	21.0, 57.0	21.0, 57.0	
C4D1 CFB					
n	15	32	38	77	
LS Mean (StdErr) [2]	-0.78 (2.300)	2.87 (1.467)	2.37 (1.330)	5.87 (1.043)	
95% CI [2]	-5.41, 3.86	-0.08, 5.83	-0.26, 5.01	3.81, 7.94	
Difference (95% CI) in CFB [2]		3.65 (-0.86, 8.17)		3.50 (0.48, 6.52)	
p-value [3]		0.110		0.023	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	32	41	77	
Mean (StdDev)	38.30 (10.396)	41.67 (7.971)	35.83 (8.591)	37.55 (10.665)	
Median	39.00	39.00	39.00	39.00	
Min, Max	21.0, 57.0	25.5, 57.0	21.0, 52.5	21.0, 57.0	
C5D1 CFB					
n	17	30	41	75	
LS Mean (StdErr) [2]	1.17 (2.649)	3.75 (1.717)	1.82 (1.177)	5.40 (0.934)	
95% CI [2]	-4.17, 6.51	0.29, 7.21	-0.52, 4.15	3.55, 7.25	
Difference (95% CI) in CFB [2]		2.58 (-2.83, 7.99)		3.58 (0.86, 6.31)	
p-value [3]		0.342		0.010	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	19	33	39	78	
Mean (StdDev)	36.17 (9.950)	43.09 (8.199)	35.32 (9.925)	39.23 (11.276)	
Median	34.51	43.49	34.51	39.00	
Min, Max	21.0, 57.0	25.5, 57.0	21.0, 57.0	21.0, 57.0	
C6D1 CFB					
n	17	31	39	76	
LS Mean (StdErr) [2]	-2.09 (2.637)	4.27 (1.703)	1.02 (1.387)	6.38 (1.080)	
95% CI [2]	-7.40, 3.22	0.84, 7.70	-1.73, 3.76	4.24, 8.52	
Difference (95% CI) in CFB [2]		6.36 (1.01, 11.71)		5.36 (2.16, 8.57)	
p-value [3]		0.021		0.001	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	18	35	40	76	
Mean (StdDev)	38.51 (12.499)	43.75 (8.430)	37.43 (9.727)	38.65 (11.304)	
Median	36.76	43.49	39.00	39.00	
Min, Max	21.0, 57.0	21.0, 57.0	21.0, 57.0	21.0, 57.0	
C7D1 CFB					
n	16	33	40	74	
LS Mean (StdErr) [2]	-0.22 (2.532)	3.59 (1.596)	2.35 (1.383)	6.12 (1.095)	
95% CI [2]	-5.32, 4.87	0.38, 6.80	-0.39, 5.09	3.95, 8.29	
Difference (95% CI) in CFB [2]		3.82 (-1.25, 8.88)		3.77 (0.61, 6.93)	
Hedges'G (95% CI) in CFB		0.40 (-0.20, 1.03)		0.41 (0.02, 0.81)	
p-value [3]		0.136		0.020	
					0.697

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	20	35	44	83	
Mean (StdDev)	36.78 (11.769)	38.32 (11.630)	30.43 (10.246)	28.47 (10.219)	
Median	36.27	36.27	26.00	26.00	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 56.8	15.7, 56.8	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	21	35	44	84	
Mean (StdDev)	38.71 (13.353)	41.84 (12.785)	34.40 (10.453)	36.27 (12.246)	
Median	36.27	46.54	36.27	36.27	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 56.8	15.7, 56.8	
C2D1 CFB					
n	19	34	43	81	
LS Mean (StdErr) [2]	0.50 (2.770)	3.40 (1.791)	3.49 (1.704)	6.21 (1.401)	
95% CI [2]	-5.06, 6.07	-0.20, 7.00	0.12, 6.87	3.44, 8.98	
Difference (95% CI) in CFB [2]		2.90 (-2.74, 8.53)		2.71 (-1.23, 6.66)	
p-value [3]		0.306		0.176	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	18	33	45	77	
Mean (StdDev)	37.98 (11.278)	42.80 (11.993)	35.81 (11.156)	37.07 (11.753)	
Median	36.27	46.54	36.27	36.27	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 56.8	15.7, 56.8	
C3D1 CFB					
n	16	33	44	75	
LS Mean (StdErr) [2]	1.57 (2.882)	5.42 (1.775)	5.60 (1.488)	9.46 (1.252)	
95% CI [2]	-4.23, 7.37	1.85, 8.99	2.65, 8.54	6.98, 11.94	
Difference (95% CI) in CFB [2]		3.85 (-2.05, 9.75)		3.86 (0.38, 7.35)	
p-value [3]		0.195		0.030	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	17	32	39	80	
Mean (StdDev)	39.29 (10.118)	42.05 (11.648)	34.69 (11.186)	36.91 (12.799)	
Median	36.27	46.54	36.27	36.27	
Min, Max	26.0, 56.8	26.0, 56.8	15.7, 56.8	15.7, 56.8	
C4D1 CFB					
n	15	31	38	78	
LS Mean (StdErr) [2]	-2.09 (3.771)	2.43 (2.492)	4.37 (1.666)	7.63 (1.304)	
95% CI [2]	-9.69, 5.52	-2.59, 7.46	1.07, 7.68	5.05, 10.22	
Difference (95% CI) in CFB [2]		4.52 (-2.70, 11.74)		3.26 (-0.52, 7.03)	
p-value [3]		0.214		0.090	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	32	41	77	
Mean (StdDev)	37.89 (14.630)	42.05 (11.352)	34.77 (11.147)	36.67 (13.581)	
Median	36.27	46.54	36.27	36.27	
Min, Max	15.7, 56.8	26.0, 56.8	15.7, 56.8	15.7, 56.8	
C5D1 CFB					
n	17	30	41	74	
LS Mean (StdErr) [2]	-2.39 (3.278)	3.68 (2.125)	4.16 (1.719)	7.80 (1.386)	
95% CI [2]	-9.00, 4.21	-0.61, 7.96	0.76, 7.57	5.06, 10.55	
Difference (95% CI) in CFB [2]		6.07 (-0.63, 12.77)		3.64 (-0.35, 7.62)	
p-value [3]		0.075		0.073	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	19	33	38	78	
Mean (StdDev)	35.73 (14.311)	44.05 (10.596)	34.65 (12.298)	37.59 (13.382)	
Median	36.27	46.54	36.27	36.27	
Min, Max	15.7, 56.8	26.0, 56.8	15.7, 56.8	15.7, 56.8	
C6D1 CFB					
n	17	31	38	75	
LS Mean (StdErr) [2]	-4.13 (3.063)	6.17 (1.979)	4.19 (1.758)	8.46 (1.379)	
95% CI [2]	-10.30, 2.04	2.18, 10.15	0.71, 7.68	5.73, 11.20	
Difference (95% CI) in CFB [2]		10.30 (4.09, 16.51)		4.27 (0.20, 8.34)	
p-value [3]		0.002		0.040	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	18	35	40	76	
Mean (StdDev)	38.55 (13.440)	42.43 (12.991)	36.78 (10.645)	37.48 (13.622)	
Median	36.27	46.54	36.27	36.27	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 56.8	15.7, 56.8	
C7D1 CFB					
n	16	33	40	73	
LS Mean (StdErr) [2]	-2.44 (2.756)	1.80 (1.738)	4.41 (1.777)	7.47 (1.431)	
95% CI [2]	-7.99, 3.11	-1.70, 5.30	0.89, 7.93	4.64, 10.31	
Difference (95% CI) in CFB [2]		4.24 (-1.28, 9.75)		3.06 (-1.00, 7.13)	
Hedges'G (95% CI) in CFB		0.40 (-0.20, 1.04)		0.26 (-0.13, 0.65)	
p-value [3]		0.129		0.138	
					0.904

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	20	35	44	84	
Mean (StdDev)	35.25 (12.359)	37.57 (9.836)	33.43 (9.820)	31.56 (8.902)	
Median	30.05	30.05	30.05	30.05	
Min, Max	19.4, 61.9	19.4, 55.5	19.4, 55.5	19.4, 55.5	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	21	35	44	84	
Mean (StdDev)	37.63 (11.214)	39.03 (10.498)	35.41 (11.021)	33.49 (10.250)	
Median	30.05	44.92	30.05	30.05	
Min, Max	19.4, 55.5	19.4, 55.5	19.4, 55.5	19.4, 55.5	
C2D1 CFB					
n	19	34	43	82	
LS Mean (StdErr) [2]	1.67 (2.660)	1.55 (1.719)	1.88 (1.355)	2.10 (1.096)	
95% CI [2]	-3.67, 7.01	-1.90, 5.00	-0.80, 4.57	-0.07, 4.26	
Difference (95% CI) in CFB [2]		-0.12 (-5.53, 5.29)		0.21 (-2.92, 3.35)	
p-value [3]		0.964		0.894	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	18	33	45	77	
Mean (StdDev)	34.18 (8.879)	40.80 (9.822)	35.05 (10.586)	35.01 (11.166)	
Median	30.05	44.92	30.05	30.05	
Min, Max	19.4, 55.5	19.4, 55.5	19.4, 55.5	19.4, 61.9	
C3D1 CFB					
n	16	33	44	76	
LS Mean (StdErr) [2]	-2.14 (2.239)	3.26 (1.379)	0.81 (1.559)	3.71 (1.290)	
95% CI [2]	-6.65, 2.37	0.48, 6.04	-2.27, 3.90	1.15, 6.26	
Difference (95% CI) in CFB [2]		5.40 (0.82, 9.98)		2.89 (-0.75, 6.54)	
p-value [3]		0.022		0.119	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	17	33	39	80	
Mean (StdDev)	38.67 (11.912)	40.35 (9.967)	34.68 (10.280)	35.28 (11.094)	
Median	30.05	44.92	30.05	30.05	
Min, Max	19.4, 61.9	19.4, 55.5	19.4, 55.5	19.4, 55.5	
C4D1 CFB					
n	15	32	38	79	
LS Mean (StdErr) [2]	-2.54 (3.012)	1.03 (1.921)	1.26 (1.631)	3.31 (1.254)	
95% CI [2]	-8.61, 3.53	-2.85, 4.90	-1.97, 4.49	0.83, 5.80	
Difference (95% CI) in CFB [2]		3.57 (-2.34, 9.48)		2.05 (-1.64, 5.74)	
p-value [3]		0.230		0.273	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	32	41	77	
Mean (StdDev)	37.76 (10.170)	40.34 (9.610)	35.18 (10.266)	36.03 (11.027)	
Median	30.05	44.92	30.05	30.05	
Min, Max	30.0, 61.9	19.4, 55.5	19.4, 55.5	19.4, 55.5	
C5D1 CFB					
n	17	30	41	75	
LS Mean (StdErr) [2]	-0.88 (3.049)	2.75 (1.976)	2.14 (1.553)	4.26 (1.232)	
95% CI [2]	-7.02, 5.27	-1.23, 6.73	-0.94, 5.21	1.82, 6.70	
Difference (95% CI) in CFB [2]		3.63 (-2.60, 9.86)		2.12 (-1.47, 5.72)	
p-value [3]		0.247		0.244	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	19	33	39	78	
Mean (StdDev)	36.87 (12.176)	41.25 (9.653)	35.44 (11.124)	36.80 (11.376)	
Median	30.05	44.92	30.05	37.48	
Min, Max	19.4, 61.9	19.4, 55.5	19.4, 55.5	19.4, 55.5	
C6D1 CFB					
n	17	31	39	76	
LS Mean (StdErr) [2]	-2.54 (3.085)	4.06 (1.993)	2.50 (1.562)	5.10 (1.216)	
95% CI [2]	-8.76, 3.67	0.05, 8.07	-0.60, 5.59	2.69, 7.51	
Difference (95% CI) in CFB [2]		6.60 (0.35, 12.86)		2.61 (-1.00, 6.22)	
p-value [3]		0.039		0.155	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	18	35	40	76	
Mean (StdDev)	37.25 (11.753)	42.06 (9.951)	35.94 (10.806)	37.12 (11.319)	
Median	30.05	44.92	30.05	44.92	
Min, Max	19.4, 55.5	19.4, 55.5	19.4, 55.5	19.4, 55.5	
C7D1 CFB					
n	16	33	40	74	
LS Mean (StdErr) [2]	-3.14 (2.750)	3.14 (1.734)	1.63 (1.690)	4.89 (1.338)	
95% CI [2]	-8.68, 2.39	-0.35, 6.64	-1.72, 4.98	2.24, 7.54	
Difference (95% CI) in CFB [2]		6.29 (0.79, 11.79)		3.26 (-0.60, 7.12)	
Hedges'G (95% CI) in CFB		0.60 (0.00, 1.25)		0.29 (-0.10, 0.68)	
p-value [3]		0.026		0.097	
					0.505

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	20	35	44	84	
Mean (StdDev)	37.27 (8.895)	37.41 (8.651)	40.24 (9.067)	36.62 (7.988)	
Median	38.25	38.25	38.25	38.25	
Min, Max	28.5, 57.8	28.5, 57.8	28.5, 57.8	28.5, 57.8	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	21	35	44	84	
Mean (StdDev)	41.04 (10.748)	40.76 (9.852)	40.24 (8.303)	38.37 (9.394)	
Median	38.25	38.25	38.25	38.25	
Min, Max	28.5, 67.5	28.5, 57.8	28.5, 57.8	28.5, 57.8	
C2D1 CFB					
n	19	34	43	82	
LS Mean (StdErr) [2]	3.91 (1.898)	4.07 (1.227)	-0.22 (1.375)	1.61 (1.112)	
95% CI [2]	0.10, 7.72	1.61, 6.54	-2.95, 2.50	-0.59, 3.81	
Difference (95% CI) in CFB [2]		0.16 (-3.70, 4.02)		1.84 (-1.34, 5.02)	
p-value [3]		0.932		0.255	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	18	33	45	77	
Mean (StdDev)	39.87 (9.008)	42.39 (10.354)	42.15 (10.059)	39.26 (9.439)	
Median	38.25	48.00	38.25	38.25	
Min, Max	28.5, 67.5	28.5, 57.8	28.5, 57.8	28.5, 57.8	
C3D1 CFB					
n	16	33	44	76	
LS Mean (StdErr) [2]	3.86 (2.113)	5.69 (1.301)	1.85 (1.338)	2.51 (1.107)	
95% CI [2]	-0.39, 8.11	3.07, 8.31	-0.80, 4.50	0.32, 4.70	
Difference (95% CI) in CFB [2]		1.83 (-2.50, 6.15)		0.66 (-2.47, 3.79)	
p-value [3]		0.399		0.678	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	17	33	39	80	
Mean (StdDev)	38.82 (9.426)	40.91 (9.837)	40.75 (8.288)	40.20 (10.457)	
Median	38.25	38.25	38.25	38.25	
Min, Max	28.5, 57.8	28.5, 57.8	28.5, 57.8	28.5, 57.8	
C4D1 CFB					
n	15	32	38	79	
LS Mean (StdErr) [2]	2.94 (2.227)	3.85 (1.420)	0.88 (1.719)	2.80 (1.322)	
95% CI [2]	-1.55, 7.42	0.98, 6.71	-2.53, 4.28	0.18, 5.41	
Difference (95% CI) in CFB [2]		0.91 (-3.46, 5.28)		1.92 (-1.97, 5.81)	
p-value [3]		0.677		0.330	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	32	41	77	
Mean (StdDev)	38.25 (9.196)	40.38 (9.510)	41.10 (9.316)	40.78 (10.303)	
Median	38.25	38.25	38.25	38.25	
Min, Max	28.5, 57.8	28.5, 57.8	28.5, 57.8	28.5, 67.5	
C5D1 CFB					
n	17	30	41	75	
LS Mean (StdErr) [2]	1.37 (2.617)	4.66 (1.696)	0.86 (1.615)	3.54 (1.282)	
95% CI [2]	-3.90, 6.64	1.24, 8.07	-2.33, 4.06	1.00, 6.08	
Difference (95% CI) in CFB [2]		3.29 (-2.06, 8.63)		2.67 (-1.07, 6.41)	
p-value [3]		0.222		0.159	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	19	33	39	78	
Mean (StdDev)	36.71 (8.762)	42.98 (10.090)	40.00 (8.915)	41.50 (10.388)	
Median	38.25	48.00	38.25	38.25	
Min, Max	28.5, 57.8	28.5, 57.8	28.5, 57.8	28.5, 67.5	
C6D1 CFB					
n	17	31	39	76	
LS Mean (StdErr) [2]	0.48 (2.560)	6.84 (1.654)	-0.30 (1.549)	3.84 (1.206)	
95% CI [2]	-4.68, 5.63	3.51, 10.17	-3.37, 2.77	1.45, 6.23	
Difference (95% CI) in CFB [2]		6.36 (1.17, 11.55)		4.14 (0.56, 7.72)	
p-value [3]		0.017		0.024	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	18	35	40	76	
Mean (StdDev)	37.17 (10.521)	41.87 (9.778)	43.13 (10.122)	41.07 (10.781)	
Median	38.25	38.25	48.00	38.25	
Min, Max	28.5, 67.5	28.5, 57.8	28.5, 57.8	28.5, 67.5	
C7D1 CFB					
n	16	33	40	74	
LS Mean (StdErr) [2]	1.71 (2.009)	5.00 (1.267)	2.56 (1.651)	3.43 (1.307)	
95% CI [2]	-2.34, 5.75	2.45, 7.55	-0.71, 5.83	0.84, 6.02	
Difference (95% CI) in CFB [2]		3.29 (-0.73, 7.31)		0.87 (-2.91, 4.64)	
Hedges'G (95% CI) in CFB		0.43 (-0.17, 1.07)		0.08 (-0.31, 0.47)	
p-value [3]		0.106		0.650	
					0.346

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	20	35	44	84	
Mean (StdDev)	40.75 (10.896)	40.53 (8.078)	34.93 (11.826)	35.11 (11.247)	
Median	36.29	36.29	36.29	36.29	
Min, Max	16.5, 56.1	26.4, 56.1	16.5, 56.1	16.5, 56.1	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	21	35	44	84	
Mean (StdDev)	41.95 (10.193)	44.22 (8.932)	38.76 (10.717)	38.65 (11.982)	
Median	46.20	46.20	36.29	36.29	
Min, Max	26.4, 56.1	26.4, 56.1	16.5, 56.1	16.5, 56.1	
C2D1 CFB					
n	19	34	43	82	
LS Mean (StdErr) [2]	3.28 (2.308)	4.89 (1.492)	2.77 (1.708)	2.55 (1.381)	
95% CI [2]	-1.35, 7.92	1.89, 7.89	-0.61, 6.15	-0.18, 5.29	
Difference (95% CI) in CFB [2]		1.61 (-3.08, 6.30)		-0.22 (-4.17, 3.73)	
p-value [3]		0.495		0.914	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	18	33	45	77	
Mean (StdDev)	41.24 (11.406)	44.10 (8.499)	40.69 (11.295)	38.60 (12.653)	
Median	41.24	46.20	36.29	36.29	
Min, Max	16.5, 56.1	26.4, 56.1	16.5, 56.1	16.5, 56.1	
C3D1 CFB					
n	16	33	44	76	
LS Mean (StdErr) [2]	3.10 (2.810)	4.75 (1.731)	5.46 (1.556)	3.43 (1.288)	
95% CI [2]	-2.56, 8.76	1.27, 8.23	2.38, 8.55	0.88, 5.98	
Difference (95% CI) in CFB [2]		1.65 (-4.10, 7.41)		-2.04 (-5.68, 1.60)	
p-value [3]		0.566		0.270	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	17	33	39	80	
Mean (StdDev)	43.28 (10.953)	44.10 (8.499)	37.81 (10.798)	38.89 (13.454)	
Median	46.20	46.20	36.29	36.29	
Min, Max	26.4, 56.1	26.4, 56.1	16.5, 56.1	16.5, 56.1	
C4D1 CFB					
n	15	32	38	79	
LS Mean (StdErr) [2]	2.32 (3.001)	3.91 (1.914)	2.82 (1.924)	3.90 (1.479)	
95% CI [2]	-3.73, 8.37	0.05, 7.77	-1.00, 6.63	0.96, 6.83	
Difference (95% CI) in CFB [2]		1.59 (-4.31, 7.48)		1.08 (-3.27, 5.43)	
p-value [3]		0.590		0.624	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	32	41	77	
Mean (StdDev)	40.98 (12.083)	46.82 (8.328)	38.70 (11.684)	40.53 (13.108)	
Median	46.20	46.20	36.29	36.29	
Min, Max	26.4, 56.1	26.4, 56.1	16.5, 56.1	16.5, 56.1	
C5D1 CFB					
n	17	30	41	75	
LS Mean (StdErr) [2]	0.64 (3.395)	8.11 (2.200)	3.23 (1.827)	4.97 (1.450)	
95% CI [2]	-6.21, 7.48	3.68, 12.55	-0.39, 6.85	2.10, 7.84	
Difference (95% CI) in CFB [2]		7.48 (0.54, 14.41)		1.74 (-2.49, 5.97)	
p-value [3]		0.035		0.417	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-ism-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	19	33	39	78	
Mean (StdDev)	39.42 (13.647)	46.20 (8.586)	38.83 (10.599)	39.97 (12.991)	
Median	36.29	46.20	36.29	46.20	
Min, Max	16.5, 56.1	26.4, 56.1	16.5, 56.1	16.5, 56.1	
C6D1 CFB					
n	17	31	39	76	
LS Mean (StdErr) [2]	0.62 (3.520)	7.54 (2.274)	3.04 (1.889)	3.78 (1.470)	
95% CI [2]	-6.47, 7.71	2.96, 12.12	-0.70, 6.78	0.86, 6.69	
Difference (95% CI) in CFB [2]		6.92 (-0.22, 14.06)		0.74 (-3.63, 5.10)	
p-value [3]		0.057		0.738	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	18	35	40	76	
Mean (StdDev)	42.90 (13.602)	46.48 (10.055)	39.01 (10.996)	40.85 (13.295)	
Median	41.24	46.20	36.29	46.20	
Min, Max	16.5, 56.1	26.4, 56.1	16.5, 56.1	16.5, 56.1	
C7D1 CFB					
n	16	33	40	74	
LS Mean (StdErr) [2]	0.94 (3.014)	5.87 (1.900)	2.44 (1.958)	4.78 (1.551)	
95% CI [2]	-5.12, 7.01	2.05, 9.70	-1.44, 6.32	1.71, 7.85	
Difference (95% CI) in CFB [2]		4.93 (-1.10, 10.96)		2.34 (-2.13, 6.82)	
Hedges'G (95% CI) in CFB		0.43 (-0.17, 1.07)		0.18 (-0.21, 0.57)	
p-value [3]		0.106		0.302	
					0.422

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-ism-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	20	35	44	84	
Mean (StdDev)	41.20 (11.779)	41.32 (10.799)	35.51 (11.709)	36.05 (11.784)	
Median	42.03	39.27	33.75	33.75	
Min, Max	17.2, 55.8	22.7, 55.8	11.7, 55.8	11.7, 55.8	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-ism-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	21	35	44	84	
Mean (StdDev)	40.06 (12.252)	43.37 (10.653)	39.90 (11.179)	39.80 (12.344)	
Median	39.27	44.79	39.27	39.27	
Min, Max	17.2, 55.8	17.2, 55.8	22.7, 55.8	11.7, 55.8	
C2D1 CFB					
n	19	34	43	82	
LS Mean (StdErr) [2]	0.32 (2.943)	2.81 (1.902)	5.09 (1.438)	4.52 (1.163)	
95% CI [2]	-5.59, 6.23	-1.01, 6.63	2.25, 7.94	2.22, 6.82	
Difference (95% CI) in CFB [2]		2.49 (-3.50, 8.47)		-0.58 (-3.90, 2.75)	
p-value [3]		0.408		0.732	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	18	33	45	77	
Mean (StdDev)	42.64 (10.897)	45.46 (10.210)	39.76 (13.093)	39.56 (12.467)	
Median	44.79	44.79	39.27	39.27	
Min, Max	22.7, 55.8	22.7, 55.8	11.7, 55.8	11.7, 55.8	
C3D1 CFB					
n	16	33	44	76	
LS Mean (StdErr) [2]	-0.88 (2.827)	3.14 (1.741)	4.93 (1.577)	5.10 (1.305)	
95% CI [2]	-6.57, 4.81	-0.36, 6.65	1.81, 8.06	2.51, 7.68	
Difference (95% CI) in CFB [2]		4.02 (-1.76, 9.81)		0.16 (-3.53, 3.85)	
p-value [3]		0.168		0.931	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	17	33	39	79	
Mean (StdDev)	42.19 (13.394)	45.46 (10.576)	37.86 (11.585)	40.81 (12.620)	
Median	44.79	50.31	33.75	44.79	
Min, Max	17.2, 55.8	17.2, 55.8	17.2, 55.8	11.7, 55.8	
C4D1 CFB					
n	15	32	38	78	
LS Mean (StdErr) [2]	-2.87 (3.427)	2.87 (2.186)	4.68 (1.781)	5.56 (1.373)	
95% CI [2]	-9.78, 4.04	-1.54, 7.27	1.15, 8.21	2.84, 8.28	
Difference (95% CI) in CFB [2]		5.74 (-0.99, 12.47)		0.88 (-3.16, 4.92)	
p-value [3]		0.093		0.668	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-ism-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	32	41	77	
Mean (StdDev)	39.85 (12.188)	44.62 (9.454)	40.89 (12.478)	41.78 (11.963)	
Median	39.27	44.79	39.27	44.79	
Min, Max	17.2, 55.8	22.7, 55.8	11.7, 55.8	11.7, 55.8	
C5D1 CFB					
n	17	30	41	75	
LS Mean (StdErr) [2]	-4.72 (2.973)	3.26 (1.927)	6.86 (1.860)	6.63 (1.476)	
95% CI [2]	-10.71, 1.27	-0.62, 7.14	3.17, 10.54	3.71, 9.56	
Difference (95% CI) in CFB [2]		7.98 (1.91, 14.06)		-0.22 (-4.53, 4.08)	
p-value [3]		0.011		0.919	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	19	33	39	78	
Mean (StdDev)	39.85 (13.380)	44.62 (9.803)	40.83 (12.971)	40.19 (12.810)	
Median	39.27	44.79	44.79	44.79	
Min, Max	11.7, 55.8	22.7, 55.8	11.7, 55.8	11.7, 55.8	
C6D1 CFB					
n	17	31	39	76	
LS Mean (StdErr) [2]	-4.06 (3.317)	2.23 (2.143)	6.00 (1.961)	4.23 (1.527)	
95% CI [2]	-10.74, 2.62	-2.08, 6.55	2.11, 9.88	1.20, 7.25	
Difference (95% CI) in CFB [2]		6.30 (-0.43, 13.02)		-1.77 (-6.30, 2.76)	
p-value [3]		0.066		0.440	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-ism-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	18	35	40	76	
Mean (StdDev)	41.11 (14.540)	45.11 (10.189)	39.13 (12.084)	40.87 (12.285)	
Median	42.03	44.79	36.51	44.79	
Min, Max	11.7, 55.8	17.2, 55.8	11.7, 55.8	11.7, 55.8	
C7D1 CFB					
n	16	33	40	74	
LS Mean (StdErr) [2]	-4.73 (2.631)	3.01 (1.659)	3.24 (1.742)	4.62 (1.380)	
95% CI [2]	-10.03, 0.56	-0.33, 6.35	-0.21, 6.69	1.89, 7.35	
Difference (95% CI) in CFB [2]		7.74 (2.48, 13.01)		1.38 (-2.60, 5.36)	
Hedges'G (95% CI) in CFB		0.77 (0.18, 1.44)		0.12 (-0.27, 0.51)	
p-value [3]		0.005		0.493	
					0.086

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	20	35	44	84	
Mean (StdDev)	43.24 (9.130)	42.20 (8.764)	40.01 (9.587)	37.93 (9.920)	
Median	39.59	39.59	39.59	39.59	
Min, Max	33.5, 57.8	21.3, 63.9	21.3, 57.8	15.3, 57.8	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	21	35	44	84	
Mean (StdDev)	43.65 (10.595)	43.24 (8.241)	40.84 (10.211)	40.10 (11.021)	
Median	45.68	45.68	39.59	39.59	
Min, Max	27.4, 57.8	33.5, 57.8	21.3, 57.8	15.3, 57.8	
C2D1 CFB					
n	19	34	43	82	
LS Mean (StdErr) [2]	2.23 (2.068)	2.15 (1.337)	1.11 (1.155)	2.71 (0.934)	
95% CI [2]	-1.93, 6.38	-0.54, 4.83	-1.18, 3.40	0.87, 4.56	
Difference (95% CI) in CFB [2]		-0.08 (-4.28, 4.13)		1.60 (-1.07, 4.27)	
p-value [3]		0.971		0.237	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	18	33	45	77	
Mean (StdDev)	44.66 (9.618)	47.34 (9.888)	41.35 (10.345)	41.49 (11.088)	
Median	45.68	51.76	39.59	45.68	
Min, Max	27.4, 57.8	21.3, 63.9	15.3, 63.9	15.3, 57.8	
C3D1 CFB					
n	16	33	44	76	
LS Mean (StdErr) [2]	-1.06 (2.496)	4.52 (1.537)	1.43 (1.355)	4.06 (1.121)	
95% CI [2]	-6.08, 3.97	1.43, 7.61	-1.25, 4.11	1.84, 6.28	
Difference (95% CI) in CFB [2]		5.58 (0.47, 10.69)		2.63 (-0.54, 5.80)	
p-value [3]		0.033		0.103	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	17	33	39	80	
Mean (StdDev)	43.17 (9.389)	46.41 (8.570)	41.62 (9.901)	42.64 (11.615)	
Median	39.59	45.68	39.59	45.68	
Min, Max	27.4, 57.8	27.4, 57.8	21.3, 63.9	15.3, 63.9	
C4D1 CFB					
n	15	32	38	79	
LS Mean (StdErr) [2]	-0.14 (2.300)	4.48 (1.467)	2.89 (1.575)	5.28 (1.211)	
95% CI [2]	-4.78, 4.50	1.53, 7.44	-0.23, 6.02	2.88, 7.68	
Difference (95% CI) in CFB [2]		4.62 (0.11, 9.14)		2.38 (-1.18, 5.95)	
p-value [3]		0.045		0.188	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	32	41	77	
Mean (StdDev)	44.72 (11.338)	45.87 (8.246)	41.23 (10.538)	42.28 (11.186)	
Median	45.68	45.68	39.59	39.59	
Min, Max	27.4, 63.9	27.4, 63.9	21.3, 63.9	15.3, 63.9	
C5D1 CFB					
n	17	30	41	75	
LS Mean (StdErr) [2]	-0.81 (2.349)	4.25 (1.523)	2.22 (1.574)	4.72 (1.250)	
95% CI [2]	-5.54, 3.93	1.18, 7.32	-0.90, 5.34	2.24, 7.19	
Difference (95% CI) in CFB [2]		5.06 (0.26, 9.86)		2.49 (-1.15, 6.14)	
p-value [3]		0.039		0.178	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	19	33	38	78	
Mean (StdDev)	43.12 (10.598)	45.86 (8.397)	42.48 (9.974)	41.39 (11.480)	
Median	39.59	45.68	39.59	45.68	
Min, Max	27.4, 57.8	27.4, 63.9	27.4, 63.9	15.3, 63.9	
C6D1 CFB					
n	17	31	38	76	
LS Mean (StdErr) [2]	-1.09 (2.093)	3.87 (1.352)	2.54 (1.646)	4.28 (1.270)	
95% CI [2]	-5.31, 3.12	1.15, 6.59	-0.72, 5.80	1.76, 6.79	
Difference (95% CI) in CFB [2]		4.96 (0.72, 9.21)		1.74 (-2.07, 5.54)	
p-value [3]		0.023		0.367	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	18	35	40	76	
Mean (StdDev)	44.66 (10.892)	46.37 (9.649)	41.27 (10.580)	42.32 (12.698)	
Median	45.68	45.68	42.64	39.59	
Min, Max	27.4, 63.9	27.4, 63.9	15.3, 63.9	15.3, 63.9	
C7D1 CFB					
n	16	33	40	74	
LS Mean (StdErr) [2]	-0.79 (2.508)	3.45 (1.581)	2.10 (1.864)	5.15 (1.476)	
95% CI [2]	-5.84, 4.26	0.27, 6.64	-1.59, 5.80	2.23, 8.08	
Difference (95% CI) in CFB [2]		4.24 (-0.78, 9.26)		3.05 (-1.21, 7.31)	
Hedges'G (95% CI) in CFB		0.44 (-0.15, 1.09)		0.24 (-0.14, 0.64)	
p-value [3]		0.096		0.159	
					0.914

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	20	35	44	83	
Mean (StdDev)	36.40 (12.007)	39.25 (12.005)	33.32 (10.361)	30.59 (8.810)	
Median	34.18	40.81	33.42	30.19	
Min, Max	14.0, 59.0	10.5, 61.8	13.8, 60.4	11.7, 50.2	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	21	35	44	84	
Mean (StdDev)	39.42 (12.215)	41.52 (12.781)	35.12 (10.442)	35.14 (11.341)	
Median	37.56	43.21	35.34	35.57	
Min, Max	20.9, 61.2	17.0, 58.2	16.5, 58.9	13.0, 58.5	
C2D1 CFB					
n	19	34	43	81	
LS Mean (StdErr) [2]	0.90 (1.927)	1.40 (1.246)	1.41 (1.143)	3.37 (0.940)	
95% CI [2]	-2.98, 4.77	-1.10, 3.90	-0.85, 3.67	1.51, 5.23	
Difference (95% CI) in CFB [2]		0.51 (-3.41, 4.42)		1.96 (-0.69, 4.61)	
p-value [3]		0.796		0.146	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	18	33	45	77	
Mean (StdDev)	36.30 (10.326)	42.37 (11.566)	35.72 (10.406)	36.12 (11.788)	
Median	34.67	43.65	35.15	36.03	
Min, Max	18.0, 60.0	15.3, 57.7	15.1, 62.6	13.3, 61.4	
C3D1 CFB					
n	16	33	44	75	
LS Mean (StdErr) [2]	-0.15 (2.041)	2.97 (1.257)	1.99 (1.097)	5.44 (0.922)	
95% CI [2]	-4.26, 3.96	0.44, 5.50	-0.19, 4.16	3.61, 7.27	
Difference (95% CI) in CFB [2]		3.12 (-1.06, 7.30)		3.45 (0.88, 6.02)	
p-value [3]		0.140		0.009	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	17	32	39	78	
Mean (StdDev)	38.34 (11.304)	42.24 (11.181)	35.49 (10.645)	36.66 (11.464)	
Median	36.16	41.54	36.24	39.47	
Min, Max	21.7, 61.5	23.1, 58.5	10.8, 57.9	12.8, 59.8	
C4D1 CFB					
n	15	31	38	76	
LS Mean (StdErr) [2]	-0.83 (2.780)	1.95 (1.837)	2.25 (1.201)	5.34 (0.959)	
95% CI [2]	-6.44, 4.78	-1.75, 5.66	-0.13, 4.63	3.43, 7.24	
Difference (95% CI) in CFB [2]		2.78 (-2.54, 8.11)		3.09 (0.36, 5.82)	
p-value [3]		0.298		0.027	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	32	41	77	
Mean (StdDev)	38.59 (12.070)	42.02 (10.971)	35.19 (10.969)	36.25 (12.385)	
Median	37.29	41.80	36.03	36.84	
Min, Max	19.0, 60.1	20.1, 60.6	13.5, 56.2	13.0, 64.3	
C5D1 CFB					
n	17	30	41	74	
LS Mean (StdErr) [2]	0.19 (2.444)	2.94 (1.584)	1.59 (1.158)	5.32 (0.934)	
95% CI [2]	-4.74, 5.11	-0.26, 6.13	-0.71, 3.88	3.47, 7.17	
Difference (95% CI) in CFB [2]		2.75 (-2.24, 7.74)		3.73 (1.04, 6.41)	
p-value [3]		0.273		0.007	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	19	33	38	78	
Mean (StdDev)	36.69 (11.614)	44.03 (10.927)	34.52 (11.082)	38.36 (12.187)	
Median	32.98	48.43	33.98	39.58	
Min, Max	19.8, 58.8	22.7, 61.0	16.4, 58.5	17.3, 59.1	
C6D1 CFB					
n	17	31	38	75	
LS Mean (StdErr) [2]	-2.35 (2.336)	5.16 (1.509)	1.05 (1.275)	6.64 (1.000)	
95% CI [2]	-7.06, 2.35	2.12, 8.20	-1.48, 3.57	4.65, 8.62	
Difference (95% CI) in CFB [2]		7.51 (2.78, 12.25)		5.59 (2.64, 8.54)	
p-value [3]		0.003		<0.001	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	18	35	40	76	
Mean (StdDev)	37.54 (12.586)	42.93 (11.373)	37.14 (10.692)	37.81 (12.374)	
Median	35.43	42.59	37.41	38.01	
Min, Max	14.5, 58.2	15.4, 63.1	19.0, 63.2	12.5, 60.6	
C7D1 CFB					
n	16	33	40	73	
LS Mean (StdErr) [2]	-2.05 (2.490)	1.80 (1.570)	2.35 (1.249)	6.22 (1.006)	
95% CI [2]	-7.06, 2.96	-1.36, 4.96	-0.12, 4.83	4.22, 8.21	
Difference (95% CI) in CFB [2]		3.84 (-1.14, 8.82)		3.86 (1.01, 6.72)	
Hedges'G (95% CI) in CFB		0.41 (-0.19, 1.04)		0.46 (0.07, 0.86)	
p-value [3]		0.127		0.008	
					0.730

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
Baseline					
n	20	35	44	83	
Mean (StdDev)	42.62 (10.032)	41.30 (9.871)	39.69 (10.701)	39.35 (10.132)	
Median	41.90	40.11	38.54	38.58	
Min, Max	27.5, 58.6	26.4, 61.2	19.2, 58.7	13.2, 61.0	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C2D1					
n	21	35	44	84	
Mean (StdDev)	42.66 (10.723)	43.50 (10.153)	42.05 (11.110)	41.16 (10.568)	
Median	43.55	43.42	42.21	40.63	
Min, Max	23.2, 58.2	25.3, 62.5	19.9, 64.4	19.0, 64.8	
C2D1 CFB					
n	19	34	43	81	
LS Mean (StdErr) [2]	2.65 (2.345)	3.78 (1.516)	2.38 (1.236)	2.32 (1.016)	
95% CI [2]	-2.05, 7.36	0.74, 6.83	-0.07, 4.83	0.31, 4.34	
Difference (95% CI) in CFB [2]		1.13 (-3.64, 5.90)		-0.06 (-2.92, 2.81)	
p-value [3]		0.636		0.969	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C3D1					
n	18	33	45	77	
Mean (StdDev)	44.61 (9.956)	46.04 (10.054)	42.98 (11.455)	41.62 (10.477)	
Median	44.50	47.52	43.42	43.46	
Min, Max	22.9, 61.6	21.7, 66.0	11.2, 63.3	13.8, 59.0	
C3D1 CFB					
n	16	33	44	75	
LS Mean (StdErr) [2]	1.03 (2.567)	4.72 (1.581)	3.52 (1.276)	3.07 (1.073)	
95% CI [2]	-4.13, 6.20	1.54, 7.91	1.00, 6.05	0.94, 5.19	
Difference (95% CI) in CFB [2]		3.69 (-1.57, 8.94)		-0.46 (-3.45, 2.53)	
p-value [3]		0.164		0.762	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C4D1					
n	17	32	39	78	
Mean (StdDev)	43.66 (10.609)	45.28 (8.774)	41.33 (9.967)	43.05 (11.785)	
Median	42.78	44.37	41.05	44.18	
Min, Max	24.2, 59.4	23.4, 60.2	22.0, 59.7	13.7, 63.9	
C4D1 CFB					
n	15	31	38	76	
LS Mean (StdErr) [2]	-0.16 (2.574)	3.58 (1.701)	3.17 (1.622)	4.44 (1.296)	
95% CI [2]	-5.35, 5.03	0.15, 7.01	-0.05, 6.38	1.88, 7.01	
Difference (95% CI) in CFB [2]		3.74 (-1.19, 8.66)		1.28 (-2.41, 4.96)	
p-value [3]		0.134		0.494	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C5D1					
n	19	32	41	77	
Mean (StdDev)	42.41 (11.211)	45.47 (8.726)	42.72 (12.138)	43.59 (11.546)	
Median	43.54	45.45	41.22	45.02	
Min, Max	18.6, 59.5	29.9, 64.4	14.1, 61.6	19.5, 62.5	
C5D1 CFB					
n	17	30	41	74	
LS Mean (StdErr) [2]	-1.65 (2.592)	5.21 (1.680)	3.92 (1.682)	4.61 (1.356)	
95% CI [2]	-6.87, 3.58	1.83, 8.60	0.59, 7.25	1.92, 7.29	
Difference (95% CI) in CFB [2]		6.86 (1.56, 12.16)		0.69 (-3.21, 4.58)	
p-value [3]		0.012		0.728	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C6D1					
n	19	33	38	78	
Mean (StdDev)	41.65 (10.952)	45.22 (9.062)	43.70 (10.701)	41.90 (11.793)	
Median	43.94	44.46	39.71	42.77	
Min, Max	24.1, 57.7	26.1, 61.4	25.4, 61.4	12.1, 61.5	
C6D1 CFB					
n	17	31	38	75	
LS Mean (StdErr) [2]	-0.93 (2.461)	4.30 (1.590)	3.95 (1.708)	2.75 (1.340)	
95% CI [2]	-5.89, 4.02	1.10, 7.50	0.57, 7.33	0.10, 5.41	
Difference (95% CI) in CFB [2]		5.24 (0.24, 10.23)		-1.20 (-5.15, 2.75)	
p-value [3]		0.040		0.549	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.5a
Change from Baseline of SF-12 by Baseline ISM Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	Test of Interaction p-value [1]
C7D1					
n	18	35	40	76	
Mean (StdDev)	43.62 (11.241)	45.99 (9.721)	42.04 (11.735)	42.88 (12.254)	
Median	44.13	45.87	42.90	43.60	
Min, Max	21.4, 64.9	25.3, 63.3	12.1, 64.6	12.0, 62.7	
C7D1 CFB					
n	16	33	40	73	
LS Mean (StdErr) [2]	-0.64 (2.125)	4.84 (1.340)	2.51 (1.745)	3.72 (1.405)	
95% CI [2]	-4.91, 3.64	2.15, 7.54	-0.95, 5.97	0.93, 6.50	
Difference (95% CI) in CFB [2]		5.48 (1.23, 9.73)		1.21 (-2.78, 5.20)	
Hedges'G (95% CI) in CFB		0.68 (0.08, 1.34)		0.10 (-0.29, 0.49)	
p-value [3]		0.013		0.550	
					0.188

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	11	25	53	94	
Mean (StdDev)	38.92 (10.274)	34.97 (11.669)	37.94 (12.713)	37.18 (11.230)	
Median	39.69	31.27	39.69	39.69	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	52	94	
Mean (StdDev)	41.63 (10.946)	38.34 (13.885)	39.52 (11.114)	40.31 (11.392)	
Median	39.69	39.69	39.69	39.69	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C2D1 CFB					
n	11	24	51	92	
LS Mean (StdErr) [2]	0.59 (2.673)	1.87 (1.532)	1.80 (1.071)	2.68 (0.847)	
95% CI [2]	-4.85, 6.04	-1.25, 4.99	-0.31, 3.92	1.00, 4.35	
Difference (95% CI) in CFB [2]		1.27 (-4.60, 7.15)		0.88 (-1.74, 3.49)	
p-value [3]		0.661		0.509	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	24	50	86	
Mean (StdDev)	40.33 (10.566)	38.28 (13.051)	38.68 (10.290)	40.96 (11.795)	
Median	39.69	39.69	39.69	39.69	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C3D1 CFB					
n	11	24	49	85	
LS Mean (StdErr) [2]	-0.54 (2.692)	3.18 (1.543)	1.24 (1.116)	3.47 (0.883)	
95% CI [2]	-6.03, 4.94	0.04, 6.32	-0.97, 3.44	1.72, 5.22	
Difference (95% CI) in CFB [2]		3.72 (-2.19, 9.64)		2.24 (-0.47, 4.94)	
p-value [3]		0.209		0.104	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	11	22	45	91	
Mean (StdDev)	41.22 (9.076)	39.30 (11.460)	38.75 (11.235)	40.98 (11.559)	
Median	39.69	39.69	39.69	39.69	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C4D1 CFB					
n	9	22	44	89	
LS Mean (StdErr) [2]	1.19 (3.533)	5.49 (2.000)	1.96 (1.249)	3.51 (0.925)	
95% CI [2]	-6.05, 8.43	1.39, 9.59	-0.51, 4.43	1.69, 5.34	
Difference (95% CI) in CFB [2]		4.30 (-3.25, 11.85)		1.55 (-1.42, 4.52)	
p-value [3]		0.253		0.303	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	25	48	84	
Mean (StdDev)	41.79 (9.577)	40.02 (13.188)	39.33 (12.867)	41.09 (11.299)	
Median	39.69	39.69	39.69	39.69	
Min, Max	31.3, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C5D1 CFB					
n	10	24	48	81	
LS Mean (StdErr) [2]	-0.42 (3.070)	4.21 (1.734)	1.60 (1.247)	4.58 (1.013)	
95% CI [2]	-6.68, 5.84	0.67, 7.74	-0.87, 4.07	2.57, 6.58	
Difference (95% CI) in CFB [2]		4.63 (-1.96, 11.21)		2.98 (-0.09, 6.04)	
p-value [3]		0.162		0.057	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	25	46	86	
Mean (StdDev)	40.39 (9.798)	40.36 (13.506)	38.22 (11.673)	42.62 (11.883)	
Median	39.69	39.69	39.69	39.69	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C6D1 CFB					
n	10	24	46	83	
LS Mean (StdErr) [2]	-1.58 (3.112)	4.73 (1.758)	0.81 (1.265)	5.20 (0.996)	
95% CI [2]	-7.92, 4.77	1.15, 8.32	-1.69, 3.32	3.23, 7.17	
Difference (95% CI) in CFB [2]		6.31 (-0.37, 12.99)		4.39 (1.29, 7.48)	
p-value [3]		0.063		0.006	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	11	24	47	87	
Mean (StdDev)	42.74 (6.807)	40.04 (13.241)	38.61 (11.979)	42.01 (11.808)	
Median	39.69	39.69	39.69	39.69	
Min, Max	31.3, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C7D1 CFB					
n	9	23	47	84	
LS Mean (StdErr) [2]	-3.24 (3.020)	3.12 (1.658)	0.45 (1.357)	4.04 (1.053)	
95% CI [2]	-9.41, 2.94	-0.27, 6.51	-2.24, 3.13	1.95, 6.12	
Difference (95% CI) in CFB [2]		6.36 (-0.17, 12.89)		3.59 (0.30, 6.88)	
Hedges'G (95% CI) in CFB		0.75 (-0.02, 1.63)		0.37 (0.02, 0.74)	
p-value [3]		0.056		0.032	
					0.762

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	11	25	53	94	
Mean (StdDev)	35.74 (7.264)	33.62 (9.255)	34.43 (7.996)	34.32 (8.325)	
Median	34.51	30.03	30.03	34.51	
Min, Max	21.0, 48.0	21.0, 57.0	21.0, 52.5	21.0, 57.0	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-tryp-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	52	94	
Mean (StdDev)	33.13 (8.275)	35.41 (10.286)	37.10 (9.753)	37.14 (10.037)	
Median	34.51	34.51	34.51	34.51	
Min, Max	21.0, 48.0	21.0, 57.0	21.0, 57.0	21.0, 57.0	
C2D1 CFB					
n	11	24	51	92	
LS Mean (StdErr) [2]	-4.86 (2.557)	1.10 (1.465)	2.91 (1.015)	3.13 (0.803)	
95% CI [2]	-10.07, 0.35	-1.89, 4.08	0.90, 4.92	1.55, 4.72	
Difference (95% CI) in CFB [2]		5.96 (0.34, 11.58)		0.22 (-2.26, 2.70)	
p-value [3]		0.038		0.859	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	24	50	86	
Mean (StdDev)	36.24 (9.618)	36.76 (9.638)	36.76 (9.946)	39.11 (10.466)	
Median	39.00	39.00	34.51	39.00	
Min, Max	21.0, 48.0	21.0, 57.0	21.0, 57.0	21.0, 57.0	
C3D1 CFB					
n	11	24	49	85	
LS Mean (StdErr) [2]	-3.79 (2.880)	2.79 (1.650)	2.65 (1.069)	5.24 (0.846)	
95% CI [2]	-9.66, 2.08	-0.57, 6.15	0.54, 4.76	3.57, 6.91	
Difference (95% CI) in CFB [2]		6.58 (0.25, 12.91)		2.59 (-0.00, 5.18)	
p-value [3]		0.042		0.050	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	11	21	45	90	
Mean (StdDev)	37.37 (6.435)	35.58 (8.855)	36.21 (10.799)	40.35 (10.500)	
Median	39.00	34.51	34.51	43.49	
Min, Max	25.5, 48.0	21.0, 52.5	21.0, 57.0	21.0, 57.0	
C4D1 CFB					
n	9	21	44	88	
LS Mean (StdErr) [2]	-0.89 (2.456)	2.89 (1.401)	2.39 (1.185)	5.88 (0.880)	
95% CI [2]	-5.93, 4.15	0.01, 5.76	0.04, 4.73	4.14, 7.63	
Difference (95% CI) in CFB [2]		3.78 (-1.53, 9.08)		3.50 (0.68, 6.32)	
p-value [3]		0.156		0.015	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	25	48	84	
Mean (StdDev)	38.26 (6.858)	38.47 (12.110)	36.20 (9.696)	38.84 (9.490)	
Median	39.00	39.00	36.76	39.00	
Min, Max	21.0, 48.0	21.0, 57.0	21.0, 57.0	21.0, 57.0	
C5D1 CFB					
n	10	24	48	81	
LS Mean (StdErr) [2]	-0.20 (2.822)	4.35 (1.594)	1.94 (1.098)	5.00 (0.892)	
95% CI [2]	-5.95, 5.56	1.10, 7.60	-0.24, 4.11	3.23, 6.77	
Difference (95% CI) in CFB [2]		4.55 (-1.51, 10.60)		3.06 (0.36, 5.77)	
p-value [3]		0.136		0.027	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	25	46	86	
Mean (StdDev)	37.51 (5.526)	37.57 (9.499)	35.10 (10.691)	41.20 (10.773)	
Median	39.00	39.00	34.51	39.00	
Min, Max	30.0, 43.5	21.0, 52.5	21.0, 57.0	21.0, 57.0	
C6D1 CFB					
n	10	24	46	83	
LS Mean (StdErr) [2]	-1.35 (2.660)	3.37 (1.503)	1.29 (1.274)	7.12 (1.003)	
95% CI [2]	-6.77, 4.08	0.30, 6.43	-1.23, 3.81	5.13, 9.10	
Difference (95% CI) in CFB [2]		4.71 (-0.99, 10.42)		5.83 (2.72, 8.94)	
p-value [3]		0.102		<0.001	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	11	24	47	87	
Mean (StdDev)	39.41 (6.492)	38.26 (12.395)	37.38 (11.327)	40.81 (10.211)	
Median	39.00	36.76	34.51	39.00	
Min, Max	30.0, 52.5	21.0, 57.0	21.0, 57.0	21.0, 57.0	
C7D1 CFB					
n	9	23	47	84	
LS Mean (StdErr) [2]	-1.65 (3.250)	3.14 (1.784)	3.09 (1.194)	6.69 (0.927)	
95% CI [2]	-8.29, 5.00	-0.51, 6.79	0.73, 5.46	4.85, 8.52	
Difference (95% CI) in CFB [2]		4.79 (-2.24, 11.82)		3.59 (0.70, 6.49)	
Hedges'G (95% CI) in CFB		0.52 (-0.25, 1.38)		0.43 (0.07, 0.80)	
p-value [3]		0.174		0.015	
					0.813

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	11	24	53	94	
Mean (StdDev)	32.53 (11.504)	31.99 (13.516)	32.39 (11.074)	31.24 (11.042)	
Median	26.00	26.00	26.00	26.00	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 56.8	15.7, 56.8	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-tryp-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	52	94	
Mean (StdDev)	37.06 (12.897)	35.45 (15.094)	35.48 (11.296)	38.56 (11.874)	
Median	36.27	36.27	36.27	36.27	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 56.8	15.7, 56.8	
C2D1 CFB					
n	11	23	51	92	
LS Mean (StdErr) [2]	5.08 (4.090)	1.87 (2.364)	2.94 (1.397)	6.84 (1.104)	
95% CI [2]	-3.26, 13.42	-2.95, 6.70	0.18, 5.70	4.66, 9.02	
Difference (95% CI) in CFB [2]		-3.20 (-12.30, 5.89)		3.90 (0.48, 7.31)	
p-value [3]		0.478		0.026	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	24	50	86	
Mean (StdDev)	39.43 (10.595)	39.69 (13.768)	35.65 (11.253)	38.54 (11.620)	
Median	36.27	41.40	36.27	36.27	
Min, Max	26.0, 56.8	15.7, 56.8	15.7, 56.8	15.7, 56.8	
C3D1 CFB					
n	11	23	49	85	
LS Mean (StdErr) [2]	5.92 (3.206)	7.25 (1.853)	2.90 (1.363)	7.26 (1.079)	
95% CI [2]	-0.62, 12.46	3.47, 11.03	0.20, 5.59	5.13, 9.39	
Difference (95% CI) in CFB [2]		1.33 (-5.80, 8.46)		4.36 (1.06, 7.67)	
p-value [3]		0.705		0.010	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	11	21	45	91	
Mean (StdDev)	33.47 (10.363)	35.29 (12.952)	36.72 (11.156)	39.09 (12.538)	
Median	36.27	36.27	36.27	46.54	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 56.8	15.7, 56.8	
C4D1 CFB					
n	9	20	44	89	
LS Mean (StdErr) [2]	-3.38 (3.388)	2.81 (2.001)	4.43 (1.585)	7.54 (1.174)	
95% CI [2]	-10.35, 3.58	-1.30, 6.93	1.29, 7.56	5.22, 9.86	
Difference (95% CI) in CFB [2]		6.19 (-1.01, 13.40)		3.11 (-0.65, 6.88)	
p-value [3]		0.089		0.104	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	25	48	84	
Mean (StdDev)	38.84 (9.914)	37.91 (12.466)	34.98 (12.822)	38.35 (13.413)	
Median	36.27	36.27	36.27	36.27	
Min, Max	26.0, 56.8	15.7, 56.8	15.7, 56.8	15.7, 56.8	
C5D1 CFB					
n	10	23	48	81	
LS Mean (StdErr) [2]	2.35 (3.727)	4.07 (2.121)	2.15 (1.537)	6.95 (1.249)	
95% CI [2]	-5.26, 9.97	-0.27, 8.40	-0.89, 5.19	4.48, 9.42	
Difference (95% CI) in CFB [2]		1.71 (-6.37, 9.79)		4.80 (1.02, 8.58)	
p-value [3]		0.668		0.013	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	25	45	86	
Mean (StdDev)	39.69 (10.114)	36.68 (13.086)	33.76 (13.347)	40.33 (12.826)	
Median	36.27	36.27	36.27	46.54	
Min, Max	26.0, 56.8	15.7, 56.8	15.7, 56.8	15.7, 56.8	
C6D1 CFB					
n	10	23	45	83	
LS Mean (StdErr) [2]	5.69 (3.817)	4.32 (2.172)	1.61 (1.523)	9.09 (1.189)	
95% CI [2]	-2.10, 13.49	-0.11, 8.76	-1.40, 4.63	6.74, 11.45	
Difference (95% CI) in CFB [2]		-1.37 (-9.64, 6.90)		7.48 (3.76, 11.20)	
p-value [3]		0.738		<0.001	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	11	24	47	87	
Mean (StdDev)	38.14 (6.193)	36.27 (16.026)	37.14 (12.456)	39.81 (12.804)	
Median	36.27	36.27	36.27	36.27	
Min, Max	26.0, 46.5	15.7, 56.8	15.7, 56.8	15.7, 56.8	
C7D1 CFB					
n	9	22	47	84	
LS Mean (StdErr) [2]	-0.06 (4.179)	0.92 (2.313)	4.17 (1.455)	8.00 (1.129)	
95% CI [2]	-8.62, 8.50	-3.82, 5.66	1.29, 7.05	5.76, 10.23	
Difference (95% CI) in CFB [2]		0.98 (-8.16, 10.11)		3.83 (0.30, 7.35)	
Hedges'G (95% CI) in CFB		0.08 (-0.72, 0.90)		0.37 (0.02, 0.74)	
p-value [3]		0.828		0.034	
					0.391

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	11	25	53	94	
Mean (StdDev)	35.84 (9.216)	33.95 (9.475)	33.61 (10.919)	33.16 (9.612)	
Median	30.05	30.05	30.05	30.05	
Min, Max	19.4, 44.9	19.4, 55.5	19.4, 61.9	19.4, 55.5	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	52	94	
Mean (StdDev)	40.01 (8.690)	35.31 (12.420)	35.15 (11.424)	35.06 (10.119)	
Median	44.92	30.05	30.05	30.05	
Min, Max	30.0, 55.5	19.4, 55.5	19.4, 55.5	19.4, 55.5	
C2D1 CFB					
n	11	24	51	92	
LS Mean (StdErr) [2]	5.67 (3.527)	0.61 (2.021)	1.20 (1.158)	2.33 (0.916)	
95% CI [2]	-1.51, 12.86	-3.50, 4.73	-1.09, 3.49	0.52, 4.15	
Difference (95% CI) in CFB [2]		-5.06 (-12.81, 2.69)		1.13 (-1.70, 3.96)	
p-value [3]		0.193		0.431	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	24	50	86	
Mean (StdDev)	38.87 (8.966)	33.41 (11.083)	33.74 (10.147)	37.68 (10.938)	
Median	44.92	30.05	30.05	37.48	
Min, Max	30.0, 55.5	19.4, 55.5	19.4, 55.5	19.4, 61.9	
C3D1 CFB					
n	11	24	49	85	
LS Mean (StdErr) [2]	6.03 (2.947)	0.26 (1.689)	-0.11 (1.321)	5.33 (1.045)	
95% CI [2]	0.03, 12.03	-3.18, 3.70	-2.72, 2.50	3.26, 7.40	
Difference (95% CI) in CFB [2]		-5.77 (-12.25, 0.71)		5.44 (2.24, 8.64)	
p-value [3]		0.079		0.001	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	11	22	45	91	
Mean (StdDev)	36.42 (9.309)	33.04 (10.086)	35.76 (11.286)	37.66 (11.049)	
Median	30.05	30.05	30.05	44.92	
Min, Max	30.0, 55.5	19.4, 44.9	19.4, 61.9	19.4, 55.5	
C4D1 CFB					
n	9	22	44	89	
LS Mean (StdErr) [2]	-0.24 (3.547)	-1.04 (2.007)	1.83 (1.443)	4.92 (1.069)	
95% CI [2]	-7.50, 7.03	-5.15, 3.07	-1.02, 4.69	2.80, 7.03	
Difference (95% CI) in CFB [2]		-0.80 (-8.38, 6.77)		3.08 (-0.34, 6.51)	
p-value [3]		0.830		0.078	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	25	48	84	
Mean (StdDev)	38.37 (9.170)	35.74 (12.030)	35.40 (10.473)	37.76 (10.397)	
Median	37.48	30.05	30.05	44.92	
Min, Max	30.0, 55.5	19.4, 55.5	19.4, 61.9	19.4, 55.5	
C5D1 CFB					
n	10	24	48	81	
LS Mean (StdErr) [2]	4.04 (3.245)	1.06 (1.833)	1.59 (1.402)	5.24 (1.139)	
95% CI [2]	-2.58, 10.66	-2.68, 4.80	-1.19, 4.36	2.99, 7.50	
Difference (95% CI) in CFB [2]		-2.97 (-9.94, 3.99)		3.66 (0.21, 7.11)	
p-value [3]		0.390		0.038	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	25	46	86	
Mean (StdDev)	42.08 (7.863)	37.10 (11.681)	34.29 (11.680)	38.42 (10.899)	
Median	44.92	44.92	30.05	44.92	
Min, Max	30.0, 55.5	19.4, 55.5	19.4, 61.9	19.4, 55.5	
C6D1 CFB					
n	10	24	46	83	
LS Mean (StdErr) [2]	6.25 (3.429)	2.72 (1.937)	0.17 (1.400)	5.39 (1.102)	
95% CI [2]	-0.74, 13.25	-1.23, 6.67	-2.60, 2.94	3.21, 7.57	
Difference (95% CI) in CFB [2]		-3.53 (-10.89, 3.82)		5.23 (1.81, 8.65)	
p-value [3]		0.335		0.003	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	11	24	47	87	
Mean (StdDev)	40.48 (8.835)	35.98 (12.229)	35.38 (11.337)	39.42 (10.729)	
Median	44.92	30.05	30.05	44.92	
Min, Max	30.0, 55.5	19.4, 55.5	19.4, 55.5	19.4, 55.5	
C7D1 CFB					
n	9	23	47	84	
LS Mean (StdErr) [2]	3.85 (3.745)	0.64 (2.055)	0.95 (1.408)	6.40 (1.093)	
95% CI [2]	-3.81, 11.51	-3.57, 4.84	-1.84, 3.73	4.24, 8.56	
Difference (95% CI) in CFB [2]		-3.21 (-11.31, 4.89)		5.45 (2.04, 8.86)	
Hedges'G (95% CI) in CFB		-0.31 (-1.14, 0.48)		0.55 (0.19, 0.92)	
p-value [3]		0.424		0.002	
					0.035

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-tryp-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	11	25	53	94	
Mean (StdDev)	43.57 (9.112)	35.13 (7.299)	38.43 (8.868)	37.32 (8.349)	
Median	48.00	38.25	38.25	38.25	
Min, Max	28.5, 57.8	28.5, 48.0	28.5, 57.8	28.5, 57.8	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-tryp-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	52	94	
Mean (StdDev)	43.50 (10.989)	37.47 (9.305)	39.75 (8.504)	39.49 (9.620)	
Median	48.00	38.25	38.25	38.25	
Min, Max	28.5, 57.8	28.5, 57.8	28.5, 67.5	28.5, 57.8	
C2D1 CFB					
n	11	24	51	92	
LS Mean (StdErr) [2]	1.17 (3.288)	3.36 (1.884)	1.31 (1.091)	2.53 (0.863)	
95% CI [2]	-5.52, 7.87	-0.48, 7.20	-0.84, 3.47	0.82, 4.23	
Difference (95% CI) in CFB [2]		2.19 (-5.04, 9.41)		1.21 (-1.46, 3.88)	
p-value [3]		0.542		0.371	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	24	50	86	
Mean (StdDev)	42.75 (12.348)	38.66 (8.856)	41.18 (9.084)	40.63 (10.030)	
Median	38.25	38.25	38.25	38.25	
Min, Max	28.5, 57.8	28.5, 48.0	28.5, 67.5	28.5, 57.8	
C3D1 CFB					
n	11	24	49	85	
LS Mean (StdErr) [2]	1.95 (3.855)	4.55 (2.209)	3.19 (1.043)	3.81 (0.825)	
95% CI [2]	-5.90, 9.80	0.05, 9.05	1.13, 5.25	2.18, 5.44	
Difference (95% CI) in CFB [2]		2.60 (-5.87, 11.07)		0.62 (-1.90, 3.15)	
p-value [3]		0.536		0.627	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	11	22	45	91	
Mean (StdDev)	41.80 (7.891)	36.92 (10.117)	39.77 (8.812)	41.25 (10.146)	
Median	48.00	33.37	38.25	38.25	
Min, Max	28.5, 48.0	28.5, 57.8	28.5, 57.8	28.5, 57.8	
C4D1 CFB					
n	9	22	44	89	
LS Mean (StdErr) [2]	0.03 (3.575)	3.07 (2.023)	2.41 (1.413)	3.79 (1.046)	
95% CI [2]	-7.29, 7.35	-1.08, 7.21	-0.39, 5.20	1.72, 5.86	
Difference (95% CI) in CFB [2]		3.03 (-4.60, 10.67)		1.39 (-1.97, 4.74)	
p-value [3]		0.422		0.416	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	25	48	84	
Mean (StdDev)	44.75 (10.467)	37.86 (9.115)	39.06 (8.732)	41.50 (10.194)	
Median	48.00	38.25	38.25	38.25	
Min, Max	28.5, 57.8	28.5, 57.8	28.5, 57.8	28.5, 67.5	
C5D1 CFB					
n	10	24	48	81	
LS Mean (StdErr) [2]	2.19 (3.417)	3.66 (1.930)	1.22 (1.384)	4.34 (1.124)	
95% CI [2]	-4.77, 9.16	-0.28, 7.59	-1.51, 3.96	2.12, 6.57	
Difference (95% CI) in CFB [2]		1.46 (-5.87, 8.79)		3.12 (-0.29, 6.52)	
p-value [3]		0.687		0.072	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	25	46	86	
Mean (StdDev)	43.94 (8.782)	38.25 (8.904)	37.61 (8.578)	43.01 (10.446)	
Median	48.00	38.25	38.25	43.13	
Min, Max	28.5, 57.8	28.5, 57.8	28.5, 57.8	28.5, 67.5	
C6D1 CFB					
n	10	24	46	83	
LS Mean (StdErr) [2]	2.74 (2.680)	4.57 (1.514)	0.29 (1.383)	5.65 (1.089)	
95% CI [2]	-2.72, 8.21	1.48, 7.66	-2.45, 3.02	3.50, 7.81	
Difference (95% CI) in CFB [2]		1.83 (-3.92, 7.58)		5.36 (1.98, 8.74)	
p-value [3]		0.521		0.002	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	11	24	47	87	
Mean (StdDev)	48.00 (9.754)	39.06 (10.337)	39.70 (10.165)	41.95 (10.438)	
Median	48.00	38.25	38.25	38.25	
Min, Max	28.5, 57.8	28.5, 57.8	28.5, 67.5	28.5, 67.5	
C7D1 CFB					
n	9	23	47	84	
LS Mean (StdErr) [2]	5.32 (3.841)	4.02 (2.108)	1.90 (1.285)	3.96 (0.997)	
95% CI [2]	-2.53, 13.18	-0.29, 8.34	-0.64, 4.44	1.99, 5.93	
Difference (95% CI) in CFB [2]		-1.30 (-9.61, 7.00)		2.06 (-1.05, 5.17)	
Hedges'G (95% CI) in CFB		-0.12 (-0.93, 0.67)		0.23 (-0.13, 0.59)	
p-value [3]		0.751		0.193	
					0.632

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	11	25	53	94	
Mean (StdDev)	37.19 (10.355)	35.10 (10.045)	36.66 (12.136)	37.13 (10.847)	
Median	36.29	36.29	36.29	36.29	
Min, Max	26.4, 56.1	16.5, 56.1	16.5, 56.1	16.5, 56.1	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	52	94	
Mean (StdDev)	37.81 (8.910)	37.87 (10.191)	40.29 (10.977)	40.93 (11.695)	
Median	36.29	36.29	41.24	36.29	
Min, Max	26.4, 56.1	16.5, 56.1	16.5, 56.1	16.5, 56.1	
C2D1 CFB					
n	11	24	51	92	
LS Mean (StdErr) [2]	3.88 (2.872)	3.64 (1.646)	3.25 (1.450)	3.64 (1.147)	
95% CI [2]	-1.97, 9.73	0.28, 6.99	0.38, 6.11	1.37, 5.91	
Difference (95% CI) in CFB [2]		-0.24 (-6.55, 6.07)		0.40 (-3.15, 3.94)	
p-value [3]		0.939		0.826	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	24	50	86	
Mean (StdDev)	41.62 (11.169)	38.35 (10.931)	40.65 (11.359)	40.78 (12.038)	
Median	46.20	36.29	36.29	46.20	
Min, Max	26.4, 56.1	16.5, 56.1	16.5, 56.1	16.5, 56.1	
C3D1 CFB					
n	11	24	49	85	
LS Mean (StdErr) [2]	5.59 (2.696)	4.63 (1.545)	4.50 (1.458)	3.39 (1.154)	
95% CI [2]	0.10, 11.08	1.48, 7.77	1.62, 7.39	1.10, 5.67	
Difference (95% CI) in CFB [2]		-0.96 (-6.89, 4.96)		-1.12 (-4.65, 2.42)	
p-value [3]		0.743		0.533	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	11	22	45	91	
Mean (StdDev)	42.59 (11.957)	37.19 (10.993)	38.71 (10.810)	41.19 (12.659)	
Median	46.20	36.29	36.29	46.20	
Min, Max	16.5, 56.1	16.5, 56.1	16.5, 56.1	16.5, 56.1	
C4D1 CFB					
n	9	22	44	89	
LS Mean (StdErr) [2]	4.11 (3.605)	3.45 (2.041)	2.53 (1.671)	4.11 (1.238)	
95% CI [2]	-3.28, 11.49	-0.73, 7.63	-0.78, 5.84	1.66, 6.56	
Difference (95% CI) in CFB [2]		-0.66 (-8.36, 7.04)		1.58 (-2.40, 5.55)	
p-value [3]		0.862		0.434	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	25	48	84	
Mean (StdDev)	42.90 (9.763)	39.85 (13.078)	38.56 (12.140)	43.13 (11.918)	
Median	41.24	36.29	36.29	46.20	
Min, Max	26.4, 56.1	16.5, 56.1	16.5, 56.1	16.5, 56.1	
C5D1 CFB					
n	10	24	48	81	
LS Mean (StdErr) [2]	7.68 (3.824)	6.20 (2.160)	1.75 (1.637)	5.99 (1.330)	
95% CI [2]	-0.12, 15.48	1.79, 10.60	-1.49, 4.99	3.36, 8.62	
Difference (95% CI) in CFB [2]		-1.49 (-9.69, 6.72)		4.24 (0.21, 8.27)	
p-value [3]		0.714		0.039	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	25	46	86	
Mean (StdDev)	39.59 (8.800)	39.85 (11.758)	38.87 (12.265)	42.40 (12.277)	
Median	36.29	46.20	36.29	46.20	
Min, Max	26.4, 56.1	16.5, 56.1	16.5, 56.1	16.5, 56.1	
C6D1 CFB					
n	10	24	46	83	
LS Mean (StdErr) [2]	4.71 (3.336)	6.20 (1.885)	2.03 (1.758)	4.67 (1.384)	
95% CI [2]	-2.09, 11.51	2.35, 10.04	-1.45, 5.51	1.93, 7.41	
Difference (95% CI) in CFB [2]		1.49 (-5.67, 8.64)		2.64 (-1.65, 6.94)	
p-value [3]		0.675		0.226	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-tryp-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	11	24	47	87	
Mean (StdDev)	42.59 (11.104)	40.00 (12.680)	39.66 (12.103)	43.35 (12.550)	
Median	46.20	46.20	36.29	46.20	
Min, Max	26.4, 56.1	16.5, 56.1	16.5, 56.1	16.5, 56.1	
C7D1 CFB					
n	9	23	47	84	
LS Mean (StdErr) [2]	3.98 (4.045)	4.42 (2.221)	2.27 (1.651)	5.81 (1.281)	
95% CI [2]	-4.29, 12.25	-0.12, 8.96	-0.99, 5.54	3.28, 8.35	
Difference (95% CI) in CFB [2]		0.44 (-8.31, 9.19)		3.54 (-0.46, 7.54)	
Hedges'G (95% CI) in CFB		0.04 (-0.76, 0.84)		0.30 (-0.05, 0.67)	
p-value [3]		0.919		0.082	
					0.736

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-tryp-a.sas Date: 15:58/07AUG2023

Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	11	25	53	94	
Mean (StdDev)	36.26 (11.408)	33.31 (11.914)	37.50 (12.138)	38.74 (11.448)	
Median	33.75	33.75	33.75	39.27	
Min, Max	22.7, 55.8	11.7, 55.8	11.7, 55.8	11.7, 55.8	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	52	94	
Mean (StdDev)	41.82 (12.467)	37.73 (10.866)	39.48 (11.250)	41.68 (12.128)	
Median	44.79	39.27	39.27	44.79	
Min, Max	22.7, 55.8	11.7, 55.8	17.2, 55.8	11.7, 55.8	
C2D1 CFB					
n	11	24	51	92	
LS Mean (StdErr) [2]	6.09 (3.868)	4.72 (2.216)	1.62 (1.255)	2.22 (0.992)	
95% CI [2]	-1.79, 13.97	0.21, 9.24	-0.86, 4.10	0.26, 4.18	
Difference (95% CI) in CFB [2]		-1.37 (-9.87, 7.13)		0.60 (-2.47, 3.67)	
p-value [3]		0.745		0.700	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	24	50	86	
Mean (StdDev)	43.09 (14.840)	38.12 (12.176)	39.93 (11.886)	42.22 (11.993)	
Median	50.31	33.75	42.03	44.79	
Min, Max	11.7, 55.8	11.7, 55.8	11.7, 55.8	11.7, 55.8	
C3D1 CFB					
n	11	24	49	85	
LS Mean (StdErr) [2]	2.64 (4.315)	4.11 (2.472)	2.89 (1.320)	3.98 (1.045)	
95% CI [2]	-6.15, 11.43	-0.93, 9.14	0.28, 5.51	1.92, 6.05	
Difference (95% CI) in CFB [2]		1.47 (-8.01, 10.95)		1.09 (-2.11, 4.29)	
p-value [3]		0.754		0.502	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	11	22	45	90	
Mean (StdDev)	45.29 (11.953)	35.26 (12.421)	37.68 (11.920)	43.87 (11.590)	
Median	50.31	33.75	33.75	44.79	
Min, Max	28.2, 55.8	17.2, 55.8	17.2, 55.8	11.7, 55.8	
C4D1 CFB					
n	9	22	44	88	
LS Mean (StdErr) [2]	8.22 (4.606)	2.21 (2.607)	1.25 (1.522)	5.01 (1.130)	
95% CI [2]	-1.22, 17.65	-3.13, 7.55	-1.76, 4.26	2.77, 7.25	
Difference (95% CI) in CFB [2]		-6.01 (-15.85, 3.83)		3.76 (0.14, 7.38)	
p-value [3]		0.221		0.042	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	25	48	84	
Mean (StdDev)	47.55 (10.392)	39.05 (10.261)	38.81 (12.200)	43.67 (11.455)	
Median	53.07	39.27	36.51	44.79	
Min, Max	28.2, 55.8	22.7, 55.8	11.7, 55.8	11.7, 55.8	
C5D1 CFB					
n	10	24	48	81	
LS Mean (StdErr) [2]	8.42 (4.429)	4.83 (2.502)	0.83 (1.554)	3.93 (1.263)	
95% CI [2]	-0.62, 17.45	-0.27, 9.93	-2.25, 3.90	1.43, 6.43	
Difference (95% CI) in CFB [2]		-3.59 (-13.09, 5.91)		3.10 (-0.72, 6.92)	
p-value [3]		0.447		0.111	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	25	46	86	
Mean (StdDev)	46.17 (11.796)	36.62 (11.828)	39.03 (13.006)	42.93 (11.901)	
Median	50.31	33.75	39.27	44.79	
Min, Max	22.7, 55.8	11.7, 55.8	11.7, 55.8	11.7, 55.8	
C6D1 CFB					
n	10	24	46	83	
LS Mean (StdErr) [2]	7.59 (4.432)	2.76 (2.504)	1.09 (1.689)	2.65 (1.330)	
95% CI [2]	-1.45, 16.63	-2.35, 7.87	-2.25, 4.43	0.02, 5.28	
Difference (95% CI) in CFB [2]		-4.83 (-14.34, 4.68)		1.56 (-2.57, 5.69)	
p-value [3]		0.308		0.456	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	11	24	47	87	
Mean (StdDev)	41.78 (11.672)	35.82 (10.894)	39.27 (13.121)	43.97 (11.464)	
Median	44.79	33.75	39.27	44.79	
Min, Max	22.7, 55.8	11.7, 55.8	11.7, 55.8	11.7, 55.8	
C7D1 CFB					
n	9	23	47	84	
LS Mean (StdErr) [2]	1.30 (4.422)	2.53 (2.427)	1.12 (1.405)	4.60 (1.090)	
95% CI [2]	-7.74, 10.35	-2.43, 7.49	-1.65, 3.90	2.44, 6.75	
Difference (95% CI) in CFB [2]		1.23 (-8.34, 10.79)		3.47 (0.07, 6.88)	
Hedges'G (95% CI) in CFB		0.10 (-0.70, 0.91)		0.35 (-0.01, 0.72)	
p-value [3]		0.795		0.046	
					0.644

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	11	25	53	94	
Mean (StdDev)	42.36 (9.171)	35.21 (9.701)	40.74 (9.622)	40.24 (9.544)	
Median	39.59	39.59	39.59	39.59	
Min, Max	33.5, 57.8	21.3, 57.8	21.3, 57.8	15.3, 63.9	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	52	94	
Mean (StdDev)	43.34 (10.693)	39.11 (10.814)	41.35 (10.316)	41.54 (10.219)	
Median	45.68	39.59	39.59	39.59	
Min, Max	21.3, 57.8	15.3, 57.8	27.4, 57.8	15.3, 57.8	
C2D1 CFB					
n	11	24	51	92	
LS Mean (StdErr) [2]	0.55 (2.632)	4.06 (1.508)	0.55 (0.998)	1.22 (0.789)	
95% CI [2]	-4.81, 5.91	0.98, 7.13	-1.42, 2.52	-0.34, 2.78	
Difference (95% CI) in CFB [2]		3.50 (-2.28, 9.29)		0.67 (-1.77, 3.11)	
p-value [3]		0.226		0.586	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	24	50	86	
Mean (StdDev)	43.81 (10.648)	39.34 (12.360)	41.91 (10.126)	44.33 (10.449)	
Median	45.68	39.59	39.59	45.68	
Min, Max	27.4, 57.8	15.3, 57.8	15.3, 63.9	21.3, 63.9	
C3D1 CFB					
n	11	24	49	85	
LS Mean (StdErr) [2]	-1.28 (2.563)	3.99 (1.468)	1.70 (1.258)	4.70 (0.996)	
95% CI [2]	-6.50, 3.94	1.00, 6.98	-0.79, 4.19	2.73, 6.67	
Difference (95% CI) in CFB [2]		5.27 (-0.36, 10.90)		3.00 (-0.05, 6.05)	
p-value [3]		0.066		0.054	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	11	22	45	91	
Mean (StdDev)	46.23 (8.365)	39.59 (10.946)	41.08 (9.805)	44.74 (10.727)	
Median	45.68	39.59	39.59	45.68	
Min, Max	33.5, 57.8	21.3, 57.8	21.3, 63.9	15.3, 63.9	
C4D1 CFB					
n	9	22	44	89	
LS Mean (StdErr) [2]	4.07 (2.786)	5.01 (1.577)	1.03 (1.361)	4.40 (1.008)	
95% CI [2]	-1.64, 9.77	1.78, 8.24	-1.67, 3.72	2.41, 6.40	
Difference (95% CI) in CFB [2]		0.95 (-5.00, 6.90)		3.38 (0.14, 6.61)	
p-value [3]		0.747		0.041	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	25	48	84	
Mean (StdDev)	47.20 (9.032)	40.57 (9.727)	41.12 (10.975)	44.16 (10.636)	
Median	48.72	39.59	39.59	45.68	
Min, Max	33.5, 57.8	27.4, 57.8	21.3, 63.9	15.3, 63.9	
C5D1 CFB					
n	10	24	48	81	
LS Mean (StdErr) [2]	1.10 (2.688)	5.13 (1.519)	0.77 (1.376)	3.77 (1.119)	
95% CI [2]	-4.38, 6.58	2.04, 8.23	-1.95, 3.49	1.56, 5.98	
Difference (95% CI) in CFB [2]		4.03 (-1.74, 9.80)		3.00 (-0.39, 6.39)	
p-value [3]		0.164		0.082	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	25	45	86	
Mean (StdDev)	48.21 (8.780)	40.32 (11.011)	41.22 (9.996)	43.41 (10.722)	
Median	48.72	39.59	39.59	45.68	
Min, Max	33.5, 57.8	15.3, 57.8	27.4, 63.9	15.3, 63.9	
C6D1 CFB					
n	10	24	45	83	
LS Mean (StdErr) [2]	3.08 (3.266)	5.13 (1.845)	0.01 (1.356)	2.77 (1.059)	
95% CI [2]	-3.58, 9.74	1.37, 8.90	-2.68, 2.69	0.67, 4.86	
Difference (95% CI) in CFB [2]		2.05 (-4.95, 9.06)		2.76 (-0.55, 6.07)	
p-value [3]		0.554		0.101	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	11	24	47	87	
Mean (StdDev)	46.23 (10.343)	40.61 (11.298)	41.41 (10.681)	44.42 (12.029)	
Median	45.68	39.59	39.59	45.68	
Min, Max	27.4, 63.9	15.3, 57.8	15.3, 63.9	15.3, 63.9	
C7D1 CFB					
n	9	23	47	84	
LS Mean (StdErr) [2]	1.48 (3.606)	4.18 (1.980)	0.79 (1.542)	4.29 (1.197)	
95% CI [2]	-5.90, 8.85	0.13, 8.23	-2.26, 3.84	1.92, 6.66	
Difference (95% CI) in CFB [2]		2.70 (-5.10, 10.50)		3.50 (-0.24, 7.24)	
Hedges'G (95% CI) in CFB		0.27 (-0.52, 1.09)		0.32 (-0.04, 0.69)	
p-value [3]		0.484		0.066	
					0.667

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	11	24	53	94	
Mean (StdDev)	35.45 (8.669)	33.99 (11.178)	34.04 (11.365)	32.95 (10.482)	
Median	36.31	32.38	31.33	33.35	
Min, Max	15.6, 45.0	19.6, 54.1	13.8, 60.4	10.5, 61.8	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	52	94	
Mean (StdDev)	36.87 (9.393)	36.14 (13.412)	36.42 (11.609)	37.25 (11.776)	
Median	38.08	37.28	35.34	38.22	
Min, Max	16.5, 47.2	18.3, 57.0	16.9, 61.2	13.0, 58.5	
C2D1 CFB					
n	11	23	51	92	
LS Mean (StdErr) [2]	0.22 (2.525)	0.26 (1.460)	2.52 (0.977)	4.35 (0.772)	
95% CI [2]	-4.93, 5.36	-2.71, 3.24	0.59, 4.45	2.83, 5.88	
Difference (95% CI) in CFB [2]		0.05 (-5.57, 5.66)		1.84 (-0.55, 4.23)	
p-value [3]		0.986		0.130	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	24	50	86	
Mean (StdDev)	37.48 (10.562)	37.36 (12.488)	35.47 (10.302)	38.17 (11.953)	
Median	38.08	38.86	34.05	39.17	
Min, Max	15.1, 53.8	15.3, 59.5	17.4, 62.6	13.3, 61.4	
C3D1 CFB					
n	11	23	49	85	
LS Mean (StdErr) [2]	1.91 (2.485)	2.83 (1.437)	1.39 (0.979)	5.24 (0.775)	
95% CI [2]	-3.16, 6.98	-0.10, 5.76	-0.55, 3.32	3.71, 6.77	
Difference (95% CI) in CFB [2]		0.92 (-4.61, 6.45)		3.85 (1.48, 6.23)	
p-value [3]		0.737		0.002	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	11	20	45	90	
Mean (StdDev)	34.76 (9.500)	37.29 (11.139)	36.74 (11.191)	38.51 (11.765)	
Median	38.71	38.99	36.16	39.64	
Min, Max	10.8, 42.7	17.6, 55.2	19.6, 61.5	12.8, 59.8	
C4D1 CFB					
n	9	19	44	88	
LS Mean (StdErr) [2]	-3.81 (2.927)	2.30 (1.742)	3.00 (1.116)	5.44 (0.829)	
95% CI [2]	-9.84, 2.21	-1.28, 5.89	0.79, 5.21	3.80, 7.08	
Difference (95% CI) in CFB [2]		6.12 (-0.19, 12.42)		2.44 (-0.22, 5.10)	
p-value [3]		0.057		0.072	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	25	48	84	
Mean (StdDev)	36.94 (8.959)	38.23 (14.193)	36.10 (11.935)	37.86 (11.670)	
Median	38.96	38.92	35.35	38.47	
Min, Max	15.9, 48.9	13.3, 64.3	13.5, 60.1	13.0, 62.4	
C5D1 CFB					
n	10	23	48	81	
LS Mean (StdErr) [2]	0.05 (2.476)	2.47 (1.409)	2.04 (1.077)	5.72 (0.875)	
95% CI [2]	-5.00, 5.11	-0.41, 5.34	-0.09, 4.17	3.99, 7.45	
Difference (95% CI) in CFB [2]		2.41 (-2.95, 7.78)		3.68 (1.03, 6.33)	
p-value [3]		0.366		0.007	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	25	45	86	
Mean (StdDev)	37.32 (8.032)	38.54 (12.825)	34.69 (11.924)	40.49 (11.873)	
Median	40.31	37.31	31.25	41.48	
Min, Max	16.9, 44.3	18.0, 59.1	16.4, 58.8	17.3, 61.0	
C6D1 CFB					
n	10	23	45	83	
LS Mean (StdErr) [2]	0.44 (2.223)	3.36 (1.265)	1.15 (1.169)	7.94 (0.912)	
95% CI [2]	-4.10, 4.98	0.78, 5.94	-1.16, 3.46	6.14, 9.75	
Difference (95% CI) in CFB [2]		2.92 (-1.90, 7.74)		6.79 (3.94, 9.65)	
p-value [3]		0.225		<0.0001	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	11	24	47	87	
Mean (StdDev)	39.47 (3.408)	38.35 (14.213)	36.75 (12.311)	39.72 (11.728)	
Median	39.39	39.91	35.26	38.83	
Min, Max	33.4, 44.7	12.5, 56.9	14.5, 63.2	13.6, 63.1	
C7D1 CFB					
n	9	22	47	84	
LS Mean (StdErr) [2]	-1.34 (2.768)	1.43 (1.532)	2.39 (1.124)	6.45 (0.873)	
95% CI [2]	-7.01, 4.33	-1.71, 4.56	0.17, 4.62	4.72, 8.18	
Difference (95% CI) in CFB [2]		2.76 (-3.29, 8.82)		4.06 (1.33, 6.78)	
Hedges'G (95% CI) in CFB		0.36 (-0.43, 1.20)		0.51 (0.15, 0.89)	
p-value [3]		0.358		0.004	
					0.401

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
Baseline					
n	11	24	53	94	
Mean (StdDev)	41.60 (10.612)	36.12 (9.305)	40.40 (10.575)	40.90 (10.052)	
Median	38.27	35.68	39.84	41.20	
Min, Max	28.0, 58.2	21.2, 61.2	19.2, 58.7	13.2, 61.0	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C2D1					
n	13	25	52	94	
Mean (StdDev)	43.83 (10.384)	39.30 (10.450)	41.86 (11.095)	42.53 (10.413)	
Median	44.76	37.47	42.21	42.35	
Min, Max	26.3, 60.7	19.0, 62.2	19.9, 64.4	19.6, 64.8	
C2D1 CFB					
n	11	23	51	92	
LS Mean (StdErr) [2]	4.54 (2.603)	4.60 (1.505)	1.10 (1.109)	1.42 (0.877)	
95% CI [2]	-0.76, 9.85	1.53, 7.67	-1.09, 3.30	-0.31, 3.15	
Difference (95% CI) in CFB [2]		0.05 (-5.74, 5.84)		0.32 (-2.39, 3.03)	
p-value [3]		0.985		0.817	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C3D1					
n	13	24	50	86	
Mean (StdDev)	45.16 (11.603)	39.46 (12.387)	43.00 (10.907)	43.92 (9.777)	
Median	49.62	38.19	43.34	45.29	
Min, Max	23.4, 59.9	13.8, 66.0	11.2, 63.3	17.7, 60.6	
C3D1 CFB					
n	11	23	49	85	
LS Mean (StdErr) [2]	2.48 (3.143)	4.17 (1.817)	3.18 (1.157)	3.58 (0.916)	
95% CI [2]	-3.93, 8.89	0.47, 7.88	0.89, 5.47	1.77, 5.39	
Difference (95% CI) in CFB [2]		1.69 (-5.30, 8.68)		0.40 (-2.41, 3.20)	
p-value [3]		0.625		0.779	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C4D1					
n	11	20	45	90	
Mean (StdDev)	47.60 (9.219)	38.04 (11.039)	40.68 (9.962)	44.96 (10.650)	
Median	51.60	38.54	40.74	46.01	
Min, Max	34.3, 58.4	13.7, 60.2	22.0, 59.7	16.0, 63.9	
C4D1 CFB					
n	9	19	44	88	
LS Mean (StdErr) [2]	6.03 (3.325)	3.37 (1.978)	1.13 (1.379)	3.91 (1.024)	
95% CI [2]	-0.82, 12.88	-0.71, 7.44	-1.60, 3.85	1.88, 5.93	
Difference (95% CI) in CFB [2]		-2.67 (-9.83, 4.49)		2.78 (-0.50, 6.06)	
p-value [3]		0.450		0.096	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C5D1					
n	12	25	48	84	
Mean (StdDev)	49.04 (9.604)	40.20 (10.854)	41.02 (11.783)	45.32 (10.550)	
Median	50.36	39.45	40.68	47.00	
Min, Max	32.4, 61.5	22.2, 64.4	14.1, 61.6	19.5, 62.5	
C5D1 CFB					
n	10	23	48	81	
LS Mean (StdErr) [2]	6.52 (3.298)	5.28 (1.877)	0.68 (1.453)	3.73 (1.180)	
95% CI [2]	-0.21, 13.26	1.44, 9.11	-2.19, 3.56	1.40, 6.07	
Difference (95% CI) in CFB [2]		-1.25 (-8.40, 5.90)		3.05 (-0.52, 6.63)	
p-value [3]		0.724		0.093	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C6D1					
n	12	25	45	86	
Mean (StdDev)	48.12 (9.594)	39.25 (11.266)	41.65 (10.702)	43.95 (10.910)	
Median	50.27	37.12	39.29	45.20	
Min, Max	31.1, 61.2	16.6, 61.4	24.1, 61.4	12.1, 61.5	
C6D1 CFB					
n	10	23	45	83	
LS Mean (StdErr) [2]	6.69 (3.211)	4.35 (1.828)	0.79 (1.467)	2.01 (1.145)	
95% CI [2]	0.14, 13.25	0.62, 8.08	-2.12, 3.69	-0.26, 4.27	
Difference (95% CI) in CFB [2]		-2.35 (-9.31, 4.62)		1.22 (-2.36, 4.80)	
p-value [3]		0.497		0.502	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	Test of Interaction p-value [1]
C7D1					
n	11	24	47	87	
Mean (StdDev)	46.42 (12.364)	39.32 (10.952)	41.62 (11.243)	45.12 (11.470)	
Median	46.80	42.91	42.07	45.21	
Min, Max	26.3, 64.6	19.6, 63.3	12.1, 64.9	12.0, 62.7	
C7D1 CFB					
n	9	22	47	84	
LS Mean (StdErr) [2]	4.46 (3.827)	4.10 (2.119)	1.06 (1.382)	3.94 (1.073)	
95% CI [2]	-3.38, 12.30	-0.24, 8.44	-1.68, 3.79	1.82, 6.06	
Difference (95% CI) in CFB [2]		-0.36 (-8.73, 8.00)		2.88 (-0.47, 6.23)	
Hedges'G (95% CI) in CFB		-0.03 (-0.85, 0.77)		0.29 (-0.06, 0.66)	
p-value [3]		0.929		0.091	
					0.597

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	60	110	4	9	
Mean (StdDev)	38.98 (12.128)	37.39 (11.220)	24.96 (4.207)	28.47 (9.407)	
Median	39.69	39.69	22.86	22.86	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 31.3	22.9, 48.1	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	61	111	4	8	
Mean (StdDev)	40.93 (10.625)	40.44 (11.711)	24.96 (4.207)	32.32 (13.064)	
Median	39.69	39.69	22.86	27.06	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 31.3	22.9, 56.5	
C2D1 CFB					
n	58	108	4	8	
LS Mean (StdErr) [2]	1.14 (1.132)	2.05 (0.887)	7.67 (1.991)	8.66 (1.570)	
95% CI [2]	-1.10, 3.37	0.29, 3.80	3.08, 12.26	5.04, 12.28	
Difference (95% CI) in CFB [2]		0.91 (-1.53, 3.35)		0.99 (-3.00, 4.98)	
p-value [3]		0.463		0.583	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	59	102	4	8	
Mean (StdDev)	39.97 (9.878)	41.17 (11.923)	24.96 (4.207)	30.22 (9.474)	
Median	39.69	39.69	22.86	27.06	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 31.3	22.9, 48.1	
C3D1 CFB					
n	56	101	4	8	
LS Mean (StdErr) [2]	0.82 (1.185)	3.45 (0.915)	-0.74 (1.991)	0.25 (1.570)	
95% CI [2]	-1.52, 3.16	1.64, 5.26	-5.33, 3.85	-3.37, 3.87	
Difference (95% CI) in CFB [2]		2.63 (0.07, 5.18)		0.99 (-3.00, 4.98)	
p-value [3]		0.044		0.583	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	52	104	4	9	
Mean (StdDev)	40.17 (10.592)	41.47 (11.226)	27.06 (4.858)	31.27 (11.131)	
Median	39.69	39.69	27.06	22.86	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 31.3	22.9, 48.1	
C4D1 CFB					
n	49	102	4	9	
LS Mean (StdErr) [2]	2.08 (1.368)	4.33 (1.027)	4.84 (4.973)	4.00 (3.941)	
95% CI [2]	-0.63, 4.78	2.30, 6.36	-6.41, 16.09	-4.92, 12.91	
Difference (95% CI) in CFB [2]		2.25 (-0.62, 5.13)		-0.84 (-10.55, 8.86)	
p-value [3]		0.124		0.849	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	56	100	4	9	
Mean (StdDev)	40.89 (11.946)	41.79 (11.369)	24.96 (4.207)	30.34 (10.680)	
Median	39.69	39.69	22.86	22.86	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 31.3	22.9, 48.1	
C5D1 CFB					
n	54	96	4	9	
LS Mean (StdErr) [2]	1.19 (1.333)	4.59 (1.037)	3.58 (3.471)	4.42 (2.751)	
95% CI [2]	-1.45, 3.82	2.54, 6.64	-4.28, 11.43	-1.81, 10.64	
Difference (95% CI) in CFB [2]		3.40 (0.52, 6.28)		0.84 (-5.93, 7.62)	
p-value [3]		0.021		0.785	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	102	4	9	
Mean (StdDev)	39.53 (11.145)	43.31 (11.752)	27.06 (4.858)	28.47 (9.407)	
Median	39.69	39.69	27.06	22.86	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 31.3	22.9, 48.1	
C6D1 CFB					
n	52	98	4	9	
LS Mean (StdErr) [2]	0.20 (1.338)	5.42 (1.027)	1.89 (3.347)	-0.63 (2.652)	
95% CI [2]	-2.45, 2.84	3.39, 7.45	-5.68, 9.47	-6.63, 5.37	
Difference (95% CI) in CFB [2]		5.23 (2.33, 8.12)		-2.52 (-9.06, 4.01)	
p-value [3]		<0.001		0.405	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	54	102	4	9	
Mean (StdDev)	40.46 (10.875)	42.57 (11.751)	24.96 (4.207)	30.34 (10.680)	
Median	39.69	39.69	22.86	22.86	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 31.3	22.9, 48.1	
C7D1 CFB					
n	52	98	4	9	
LS Mean (StdErr) [2]	-0.24 (1.450)	3.83 (1.095)	4.00 (3.347)	5.68 (2.652)	
95% CI [2]	-3.11, 2.62	1.67, 5.99	-3.58, 11.57	-0.32, 11.68	
Difference (95% CI) in CFB [2]		4.07 (0.99, 7.16)		1.68 (-4.85, 8.22)	
Hedges'G (95% CI) in CFB		0.38 (0.04, 0.73)		0.21 (-1.07, 1.58)	
p-value [3]		0.010		0.574	
					0.574

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	60	110	4	9	
Mean (StdDev)	35.26 (7.628)	34.64 (8.502)	25.54 (5.184)	28.53 (6.349)	
Median	34.51	34.51	25.54	25.54	
Min, Max	21.0, 52.5	21.0, 57.0	21.0, 30.0	21.0, 39.0	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	61	111	4	8	
Mean (StdDev)	36.87 (9.580)	37.14 (10.120)	27.78 (2.592)	31.71 (8.291)	
Median	34.51	39.00	27.78	30.03	
Min, Max	21.0, 57.0	21.0, 57.0	25.5, 30.0	21.0, 48.0	
C2D1 CFB					
n	58	108	4	8	
LS Mean (StdErr) [2]	0.72 (1.088)	1.72 (0.853)	5.28 (3.372)	6.47 (2.658)	
95% CI [2]	-1.43, 2.86	0.03, 3.40	-2.49, 13.06	0.34, 12.60	
Difference (95% CI) in CFB [2]		1.00 (-1.35, 3.35)		1.19 (-5.58, 7.95)	
p-value [3]		0.401		0.696	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	59	102	4	8	
Mean (StdDev)	37.18 (9.903)	39.00 (10.342)	28.90 (2.245)	33.39 (8.568)	
Median	39.00	39.00	30.03	32.27	
Min, Max	21.0, 57.0	21.0, 57.0	25.5, 30.0	21.0, 48.0	
C3D1 CFB					
n	56	101	4	8	
LS Mean (StdErr) [2]	1.29 (1.182)	4.11 (0.913)	5.35 (2.768)	7.20 (2.182)	
95% CI [2]	-1.05, 3.62	2.30, 5.91	-1.03, 11.73	2.16, 12.23	
Difference (95% CI) in CFB [2]		2.82 (0.27, 5.37)		1.85 (-3.70, 7.40)	
p-value [3]		0.030		0.465	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	52	102	4	9	
Mean (StdDev)	37.28 (9.906)	39.84 (10.317)	25.54 (3.666)	35.01 (10.149)	
Median	39.00	39.00	25.54	34.51	
Min, Max	21.0, 57.0	21.0, 57.0	21.0, 30.0	21.0, 48.0	
C4D1 CFB					
n	49	100	4	9	
LS Mean (StdErr) [2]	1.74 (1.236)	4.71 (0.937)	1.01 (5.221)	6.40 (4.137)	
95% CI [2]	-0.70, 4.18	2.86, 6.57	-10.80, 12.82	-2.96, 15.76	
Difference (95% CI) in CFB [2]		2.98 (0.37, 5.58)		5.39 (-4.80, 15.58)	
p-value [3]		0.025		0.262	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	56	100	4	9	
Mean (StdDev)	37.40 (8.955)	39.09 (10.189)	25.54 (3.666)	35.01 (8.531)	
Median	39.00	39.00	25.54	39.00	
Min, Max	21.0, 57.0	21.0, 57.0	21.0, 30.0	21.0, 43.5	
C5D1 CFB					
n	54	96	4	9	
LS Mean (StdErr) [2]	1.67 (1.182)	4.57 (0.920)	-0.45 (3.538)	7.63 (2.804)	
95% CI [2]	-0.67, 4.01	2.75, 6.39	-8.45, 7.55	1.29, 13.97	
Difference (95% CI) in CFB [2]		2.90 (0.34, 5.45)		8.08 (1.18, 14.99)	
p-value [3]		0.027		0.027	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	102	4	9	
Mean (StdDev)	36.34 (9.770)	41.20 (10.547)	25.54 (3.666)	31.02 (4.906)	
Median	34.51	39.00	25.54	30.03	
Min, Max	21.0, 57.0	21.0, 57.0	21.0, 30.0	25.5, 39.0	
C6D1 CFB					
n	52	98	4	9	
LS Mean (StdErr) [2]	0.33 (1.326)	5.92 (1.018)	-1.23 (3.034)	1.91 (2.405)	
95% CI [2]	-2.29, 2.95	3.91, 7.93	-8.10, 5.63	-3.53, 7.35	
Difference (95% CI) in CFB [2]		5.60 (2.73, 8.46)		3.14 (-2.78, 9.06)	
p-value [3]		<0.001		0.261	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	54	102	4	9	
Mean (StdDev)	38.84 (10.094)	40.85 (10.634)	23.29 (4.489)	33.52 (9.727)	
Median	39.00	39.00	21.05	30.03	
Min, Max	21.0, 57.0	21.0, 57.0	21.0, 30.0	21.0, 52.5	
C7D1 CFB					
n	52	98	4	9	
LS Mean (StdErr) [2]	2.08 (1.302)	5.23 (0.982)	3.03 (4.888)	10.21 (3.873)	
95% CI [2]	-0.50, 4.65	3.29, 7.17	-8.03, 14.09	1.45, 18.98	
Difference (95% CI) in CFB [2]		3.15 (0.38, 5.92)		7.18 (-2.36, 16.72)	
Hedges'G (95% CI) in CFB		0.33 (-0.01, 0.67)		0.60 (-0.62, 2.09)	
p-value [3]		0.026		0.123	
					0.397

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	60	109	4	9	
Mean (StdDev)	33.19 (10.912)	32.03 (11.543)	20.86 (5.930)	23.72 (8.559)	
Median	36.27	26.00	20.86	26.00	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 26.0	15.7, 36.3	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	61	111	4	8	
Mean (StdDev)	36.10 (11.634)	38.67 (12.460)	31.13 (10.270)	27.28 (10.178)	
Median	36.27	36.27	36.27	26.00	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 36.3	15.7, 46.5	
C2D1 CFB					
n	58	107	4	8	
LS Mean (StdErr) [2]	1.20 (1.493)	4.82 (1.181)	18.43 (6.936)	7.55 (5.469)	
95% CI [2]	-1.75, 4.15	2.49, 7.15	2.43, 34.42	-5.06, 20.16	
Difference (95% CI) in CFB [2]		3.62 (0.39, 6.84)		-10.87 (-24.79, 3.04)	
p-value [3]		0.028		0.109	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	59	102	4	8	
Mean (StdDev)	37.14 (11.004)	39.69 (11.682)	26.00 (8.386)	27.28 (11.564)	
Median	36.27	46.54	26.00	26.00	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 36.3	15.7, 46.5	
C3D1 CFB					
n	56	100	4	8	
LS Mean (StdErr) [2]	3.32 (1.413)	7.64 (1.100)	13.90 (4.774)	9.06 (3.764)	
95% CI [2]	0.53, 6.11	5.47, 9.82	2.89, 24.90	0.38, 17.74	
Difference (95% CI) in CFB [2]		4.33 (1.28, 7.37)		-4.83 (-14.41, 4.74)	
p-value [3]		0.006		0.278	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	52	103	4	9	
Mean (StdDev)	36.47 (11.231)	39.66 (12.151)	31.13 (5.930)	23.72 (8.559)	
Median	36.27	46.54	31.13	26.00	
Min, Max	15.7, 56.8	15.7, 56.8	26.0, 36.3	15.7, 36.3	
C4D1 CFB					
n	49	100	4	9	
LS Mean (StdErr) [2]	1.45 (1.634)	6.02 (1.259)	15.15 (4.795)	1.80 (3.800)	
95% CI [2]	-1.78, 4.68	3.53, 8.50	4.30, 26.00	-6.80, 10.39	
Difference (95% CI) in CFB [2]		4.56 (1.14, 7.99)		-13.35 (-22.71, -3.99)	
p-value [3]		0.009		0.010	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	56	100	4	9	
Mean (StdDev)	36.45 (12.308)	39.35 (12.851)	26.00 (8.386)	26.00 (10.270)	
Median	36.27	36.27	26.00	26.00	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 36.3	15.7, 46.5	
C5D1 CFB					
n	54	95	4	9	
LS Mean (StdErr) [2]	1.51 (1.637)	6.26 (1.284)	8.99 (4.525)	3.85 (3.585)	
95% CI [2]	-1.72, 4.75	3.72, 8.80	-1.25, 19.22	-4.26, 11.96	
Difference (95% CI) in CFB [2]		4.75 (1.21, 8.29)		-5.14 (-13.97, 3.69)	
p-value [3]		0.009		0.221	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	53	102	4	9	
Mean (StdDev)	36.27 (12.416)	40.60 (12.469)	18.30 (5.135)	27.14 (11.982)	
Median	36.27	46.54	15.73	26.00	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 26.0	15.7, 46.5	
C6D1 CFB					
n	51	97	4	9	
LS Mean (StdErr) [2]	1.33 (1.614)	7.45 (1.245)	1.28 (5.174)	6.42 (4.100)	
95% CI [2]	-1.86, 4.52	4.99, 9.91	-10.42, 12.99	-2.86, 15.69	
Difference (95% CI) in CFB [2]		6.12 (2.62, 9.61)		5.14 (-4.96, 15.23)	
p-value [3]		<0.001		0.280	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	54	102	4	9	
Mean (StdDev)	38.17 (11.299)	40.09 (13.397)	26.00 (8.386)	27.14 (9.531)	
Median	36.27	46.54	26.00	26.00	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 36.3	15.7, 46.5	
C7D1 CFB					
n	52	97	4	9	
LS Mean (StdErr) [2]	1.46 (1.607)	5.15 (1.224)	8.22 (4.762)	4.11 (3.774)	
95% CI [2]	-1.72, 4.64	2.73, 7.57	-2.56, 18.99	-4.43, 12.64	
Difference (95% CI) in CFB [2]		3.69 (0.27, 7.11)		-4.11 (-13.40, 5.19)	
Hedges'G (95% CI) in CFB		0.31 (-0.03, 0.65)		-0.35 (-1.77, 0.90)	
p-value [3]		0.035		0.343	
					0.325

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	60	110	4	9	
Mean (StdDev)	34.79 (10.418)	33.75 (9.564)	22.08 (5.311)	28.16 (8.121)	
Median	30.05	30.05	19.42	30.05	
Min, Max	19.4, 61.9	19.4, 55.5	19.4, 30.0	19.4, 44.9	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	61	111	4	8	
Mean (StdDev)	36.87 (10.910)	35.44 (10.521)	24.73 (6.133)	30.58 (11.170)	
Median	30.05	30.05	24.73	30.05	
Min, Max	19.4, 55.5	19.4, 55.5	19.4, 30.0	19.4, 55.5	
C2D1 CFB					
n	58	108	4	8	
LS Mean (StdErr) [2]	1.49 (1.255)	1.55 (0.984)	13.53 (4.196)	10.72 (3.308)	
95% CI [2]	-0.99, 3.97	-0.39, 3.50	3.85, 23.20	3.09, 18.35	
Difference (95% CI) in CFB [2]		0.06 (-2.65, 2.77)		-2.81 (-11.23, 5.61)	
p-value [3]		0.964		0.463	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	59	102	4	8	
Mean (StdDev)	35.48 (9.944)	37.04 (11.076)	24.73 (6.133)	32.97 (10.830)	
Median	30.05	30.05	24.73	30.05	
Min, Max	19.4, 55.5	19.4, 61.9	19.4, 30.0	19.4, 44.9	
C3D1 CFB					
n	56	101	4	8	
LS Mean (StdErr) [2]	-0.15 (1.382)	3.28 (1.067)	6.22 (6.421)	7.84 (5.063)	
95% CI [2]	-2.88, 2.58	1.17, 5.39	-8.59, 21.02	-3.83, 19.52	
Difference (95% CI) in CFB [2]		3.43 (0.45, 6.41)		1.62 (-11.26, 14.51)	
p-value [3]		0.024		0.779	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	52	104	4	9	
Mean (StdDev)	36.75 (10.688)	36.93 (10.892)	24.73 (6.133)	34.77 (12.469)	
Median	30.05	30.05	24.73	44.92	
Min, Max	19.4, 61.9	19.4, 55.5	19.4, 30.0	19.4, 44.9	
C4D1 CFB					
n	49	102	4	9	
LS Mean (StdErr) [2]	0.61 (1.518)	2.45 (1.140)	7.22 (7.881)	9.99 (6.245)	
95% CI [2]	-2.39, 3.61	0.20, 4.71	-10.60, 25.05	-4.14, 24.11	
Difference (95% CI) in CFB [2]		1.84 (-1.35, 5.04)		2.76 (-12.62, 18.14)	
p-value [3]		0.256		0.694	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	56	100	4	9	
Mean (StdDev)	36.61 (10.236)	37.67 (10.643)	27.39 (5.311)	33.11 (11.929)	
Median	30.05	44.92	30.05	30.05	
Min, Max	19.4, 61.9	19.4, 55.5	19.4, 30.0	19.4, 44.9	
C5D1 CFB					
n	54	96	4	9	
LS Mean (StdErr) [2]	1.16 (1.435)	3.59 (1.117)	11.26 (9.165)	10.41 (7.263)	
95% CI [2]	-1.67, 4.00	1.38, 5.79	-9.47, 31.99	-6.02, 26.84	
Difference (95% CI) in CFB [2]		2.42 (-0.68, 5.53)		-0.85 (-18.74, 17.04)	
p-value [3]		0.125		0.917	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	102	4	9	
Mean (StdDev)	36.93 (11.066)	38.90 (10.993)	22.08 (5.311)	29.34 (7.436)	
Median	30.05	44.92	19.42	30.05	
Min, Max	19.4, 61.9	19.4, 55.5	19.4, 30.0	19.4, 44.9	
C6D1 CFB					
n	52	98	4	9	
LS Mean (StdErr) [2]	1.13 (1.470)	4.93 (1.128)	-0.58 (7.695)	0.90 (6.098)	
95% CI [2]	-1.77, 4.04	2.70, 7.16	-17.99, 16.82	-12.89, 14.70	
Difference (95% CI) in CFB [2]		3.79 (0.61, 6.97)		1.49 (-13.53, 16.50)	
p-value [3]		0.020		0.828	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	54	102	4	9	
Mean (StdDev)	37.40 (10.609)	39.11 (11.206)	22.08 (5.311)	33.82 (9.000)	
Median	30.05	44.92	19.42	30.05	
Min, Max	19.4, 55.5	19.4, 55.5	19.4, 30.0	19.4, 44.9	
C7D1 CFB					
n	52	98	4	9	
LS Mean (StdErr) [2]	0.25 (1.507)	4.06 (1.137)	4.94 (8.670)	8.98 (6.870)	
95% CI [2]	-2.72, 3.23	1.81, 6.31	-14.67, 24.55	-6.57, 24.52	
Difference (95% CI) in CFB [2]		3.81 (0.60, 7.01)		4.04 (-12.88, 20.96)	
Hedges'G (95% CI) in CFB		0.34 (0.00, 0.69)		0.19 (-1.09, 1.56)	
p-value [3]		0.020		0.602	
					0.760

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	60	110	4	9	
Mean (StdDev)	39.71 (9.126)	37.10 (8.116)	33.37 (5.631)	33.91 (8.602)	
Median	38.25	38.25	33.37	28.50	
Min, Max	28.5, 57.8	28.5, 57.8	28.5, 38.2	28.5, 48.0	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	61	111	4	8	
Mean (StdDev)	40.97 (9.103)	39.30 (9.607)	33.37 (5.631)	35.81 (8.646)	
Median	38.25	38.25	33.37	33.37	
Min, Max	28.5, 67.5	28.5, 57.8	28.5, 38.2	28.5, 48.0	
C2D1 CFB					
n	58	108	4	8	
LS Mean (StdErr) [2]	1.23 (1.215)	2.82 (0.952)	-0.86 (2.308)	0.29 (1.820)	
95% CI [2]	-1.17, 3.63	0.94, 4.70	-6.18, 4.46	-3.91, 4.48	
Difference (95% CI) in CFB [2]		1.59 (-1.03, 4.22)		1.15 (-3.48, 5.78)	
p-value [3]		0.231		0.583	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	59	102	4	8	
Mean (StdDev)	41.72 (9.881)	40.64 (9.844)	38.25 (7.964)	34.59 (7.257)	
Median	38.25	38.25	38.25	33.37	
Min, Max	28.5, 67.5	28.5, 57.8	28.5, 48.0	28.5, 48.0	
C3D1 CFB					
n	56	101	4	8	
LS Mean (StdErr) [2]	2.46 (1.227)	4.08 (0.947)	5.45 (4.092)	1.43 (3.227)	
95% CI [2]	0.03, 4.88	2.21, 5.96	-3.99, 14.89	-6.01, 8.87	
Difference (95% CI) in CFB [2]		1.63 (-1.02, 4.27)		-4.02 (-12.23, 4.19)	
p-value [3]		0.226		0.292	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	52	104	4	9	
Mean (StdDev)	40.31 (8.711)	40.69 (10.239)	38.25 (7.964)	37.17 (10.281)	
Median	38.25	38.25	38.25	38.25	
Min, Max	28.5, 57.8	28.5, 57.8	28.5, 48.0	28.5, 57.8	
C4D1 CFB					
n	49	102	4	9	
LS Mean (StdErr) [2]	0.86 (1.472)	2.96 (1.105)	9.27 (8.118)	8.29 (6.433)	
95% CI [2]	-2.05, 3.77	0.77, 5.14	-9.10, 27.63	-6.26, 22.84	
Difference (95% CI) in CFB [2]		2.10 (-1.00, 5.19)		-0.98 (-16.82, 14.87)	
p-value [3]		0.183		0.892	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	56	100	4	9	
Mean (StdDev)	40.86 (9.205)	40.98 (10.100)	30.93 (4.877)	37.17 (9.051)	
Median	38.25	38.25	28.50	38.25	
Min, Max	28.5, 57.8	28.5, 67.5	28.5, 38.2	28.5, 57.8	
C5D1 CFB					
n	54	96	4	9	
LS Mean (StdErr) [2]	1.17 (1.476)	3.95 (1.149)	1.22 (4.914)	6.10 (3.894)	
95% CI [2]	-1.74, 4.09	1.68, 6.22	-9.90, 12.34	-2.71, 14.90	
Difference (95% CI) in CFB [2]		2.78 (-0.41, 5.97)		4.88 (-4.71, 14.47)	
p-value [3]		0.087		0.280	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	102	4	9	
Mean (StdDev)	39.51 (8.897)	42.36 (10.219)	30.93 (4.877)	37.17 (10.281)	
Median	38.25	38.25	28.50	38.25	
Min, Max	28.5, 57.8	28.5, 67.5	28.5, 38.2	28.5, 57.8	
C6D1 CFB					
n	52	98	4	9	
LS Mean (StdErr) [2]	0.06 (1.406)	5.03 (1.079)	1.71 (5.765)	7.56 (4.568)	
95% CI [2]	-2.72, 2.84	2.90, 7.16	-11.34, 14.75	-2.78, 17.89	
Difference (95% CI) in CFB [2]		4.97 (1.93, 8.01)		5.85 (-5.40, 17.10)	
p-value [3]		0.002		0.269	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	54	102	4	9	
Mean (StdDev)	41.86 (10.429)	41.40 (10.557)	33.37 (9.754)	40.42 (9.479)	
Median	38.25	38.25	28.50	38.25	
Min, Max	28.5, 67.5	28.5, 67.5	28.5, 48.0	28.5, 57.8	
C7D1 CFB					
n	52	98	4	9	
LS Mean (StdErr) [2]	2.29 (1.432)	3.66 (1.080)	1.71 (5.765)	7.56 (4.568)	
95% CI [2]	-0.54, 5.12	1.53, 5.80	-11.34, 14.75	-2.78, 17.89	
Difference (95% CI) in CFB [2]		1.37 (-1.68, 4.41)		5.85 (-5.40, 17.10)	
Hedges'G (95% CI) in CFB		0.13 (-0.21, 0.47)		0.41 (-0.83, 1.85)	
p-value [3]		0.376		0.269	
					0.360

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	60	110	4	9	
Mean (StdDev)	37.94 (11.128)	37.01 (10.464)	18.94 (4.957)	32.98 (13.115)	
Median	36.29	36.29	16.46	36.29	
Min, Max	16.5, 56.1	16.5, 56.1	16.5, 26.4	16.5, 56.1	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	61	111	4	8	
Mean (StdDev)	40.19 (10.751)	40.57 (11.392)	33.81 (4.957)	36.29 (11.850)	
Median	36.29	36.29	36.29	36.29	
Min, Max	16.5, 56.1	16.5, 56.1	26.4, 36.3	16.5, 56.1	
C2D1 CFB					
n	58	108	4	8	
LS Mean (StdErr) [2]	1.70 (1.456)	3.46 (1.142)	12.54 (7.039)	-0.87 (5.550)	
95% CI [2]	-1.17, 4.58	1.21, 5.72	-3.69, 28.77	-13.67, 11.92	
Difference (95% CI) in CFB [2]		1.76 (-1.38, 4.90)		-13.41 (-27.53, 0.71)	
p-value [3]		0.271		0.060	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	59	102	4	8	
Mean (StdDev)	41.16 (11.404)	40.76 (11.557)	36.29 (8.095)	33.81 (13.768)	
Median	36.29	46.20	36.29	36.29	
Min, Max	16.5, 56.1	16.5, 56.1	26.4, 46.2	16.5, 56.1	
C3D1 CFB					
n	56	101	4	8	
LS Mean (StdErr) [2]	3.29 (1.437)	3.92 (1.110)	21.72 (4.898)	1.02 (3.862)	
95% CI [2]	0.45, 6.13	1.73, 6.12	10.43, 33.02	-7.88, 9.93	
Difference (95% CI) in CFB [2]		0.64 (-2.46, 3.74)		-20.70 (-30.53, -10.88)	
p-value [3]		0.685		0.001	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	52	104	4	9	
Mean (StdDev)	40.48 (10.815)	41.24 (12.279)	26.37 (0.000)	30.78 (10.051)	
Median	36.29	46.20	26.37	36.29	
Min, Max	16.5, 56.1	16.5, 56.1	26.4, 26.4	16.5, 46.2	
C4D1 CFB					
n	49	102	4	9	
LS Mean (StdErr) [2]	2.17 (1.734)	4.43 (1.302)	1.98 (4.597)	-8.92 (3.643)	
95% CI [2]	-1.25, 5.60	1.86, 7.01	-8.42, 12.38	-17.16, -0.68	
Difference (95% CI) in CFB [2]		2.26 (-1.39, 5.91)		-10.91 (-19.88, -1.93)	
p-value [3]		0.223		0.022	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	56	100	4	9	
Mean (StdDev)	40.36 (11.620)	42.53 (12.175)	26.37 (0.000)	40.69 (13.219)	
Median	36.29	46.20	26.37	46.20	
Min, Max	16.5, 56.1	16.5, 56.1	26.4, 26.4	16.5, 56.1	
C5D1 CFB					
n	54	96	4	9	
LS Mean (StdErr) [2]	1.90 (1.723)	5.89 (1.341)	7.19 (7.126)	4.21 (5.646)	
95% CI [2]	-1.50, 5.31	3.24, 8.54	-8.93, 23.31	-8.56, 16.99	
Difference (95% CI) in CFB [2]		3.99 (0.26, 7.72)		-2.97 (-16.88, 10.93)	
p-value [3]		0.036		0.640	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	102	4	9	
Mean (StdDev)	40.32 (10.812)	42.51 (12.076)	21.41 (5.724)	34.08 (10.835)	
Median	36.29	46.20	21.41	36.29	
Min, Max	16.5, 56.1	16.5, 56.1	16.5, 26.4	16.5, 46.2	
C6D1 CFB					
n	52	98	4	9	
LS Mean (StdErr) [2]	1.86 (1.779)	5.35 (1.366)	-4.71 (7.907)	-6.69 (6.265)	
95% CI [2]	-1.65, 5.38	2.65, 8.05	-22.60, 13.18	-20.87, 7.48	
Difference (95% CI) in CFB [2]		3.49 (-0.36, 7.34)		-1.98 (-17.41, 13.45)	
p-value [3]		0.075		0.778	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	54	102	4	9	
Mean (StdDev)	41.43 (11.351)	43.38 (12.272)	23.89 (4.957)	34.08 (13.825)	
Median	36.29	46.20	26.37	36.29	
Min, Max	16.5, 56.1	16.5, 56.1	16.5, 26.4	16.5, 56.1	
C7D1 CFB					
n	52	98	4	9	
LS Mean (StdErr) [2]	1.41 (1.767)	5.34 (1.333)	4.21 (6.788)	0.25 (5.379)	
95% CI [2]	-2.08, 4.90	2.71, 7.98	-11.14, 19.57	-11.92, 12.42	
Difference (95% CI) in CFB [2]		3.93 (0.17, 7.69)		-3.97 (-17.21, 9.28)	
Hedges'G (95% CI) in CFB		0.30 (-0.04, 0.65)		-0.24 (-1.62, 1.04)	
p-value [3]		0.040		0.515	
					0.250

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	60	110	4	9	
Mean (StdDev)	37.34 (12.228)	37.97 (11.604)	36.51 (7.125)	33.14 (12.779)	
Median	33.75	39.27	36.51	33.75	
Min, Max	11.7, 55.8	11.7, 55.8	28.2, 44.8	11.7, 55.8	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	61	111	4	8	
Mean (StdDev)	40.36 (11.392)	40.91 (12.036)	33.75 (11.922)	39.96 (11.209)	
Median	39.27	44.79	36.51	42.03	
Min, Max	17.2, 55.8	11.7, 55.8	17.2, 44.8	22.7, 55.8	
C2D1 CFB					
n	58	108	4	8	
LS Mean (StdErr) [2]	3.38 (1.338)	3.16 (1.049)	1.62 (8.838)	9.58 (6.968)	
95% CI [2]	0.73, 6.02	1.09, 5.23	-18.76, 22.00	-6.49, 25.65	
Difference (95% CI) in CFB [2]		-0.21 (-3.10, 2.67)		7.95 (-9.78, 25.68)	
p-value [3]		0.884		0.331	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	59	102	4	8	
Mean (StdDev)	41.24 (12.373)	41.38 (11.907)	30.99 (11.489)	40.65 (15.258)	
Median	44.79	44.79	30.99	47.55	
Min, Max	11.7, 55.8	11.7, 55.8	17.2, 44.8	22.7, 55.8	
C3D1 CFB					
n	56	101	4	8	
LS Mean (StdErr) [2]	4.12 (1.453)	3.98 (1.121)	-0.97 (7.790)	11.36 (6.142)	
95% CI [2]	1.25, 6.99	1.76, 6.19	-18.94, 16.99	-2.80, 25.53	
Difference (95% CI) in CFB [2]		-0.14 (-3.27, 2.99)		12.34 (-3.29, 27.96)	
p-value [3]		0.928		0.106	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	52	103	4	9	
Mean (StdDev)	39.91 (12.054)	42.70 (12.000)	29.61 (11.378)	36.21 (13.550)	
Median	39.27	44.79	28.23	39.27	
Min, Max	17.2, 55.8	17.2, 55.8	17.2, 44.8	11.7, 55.8	
C4D1 CFB					
n	49	101	4	9	
LS Mean (StdErr) [2]	3.91 (1.634)	5.03 (1.227)	-4.69 (8.248)	-0.28 (6.536)	
95% CI [2]	0.68, 7.14	2.61, 7.46	-23.35, 13.97	-15.06, 14.51	
Difference (95% CI) in CFB [2]		1.12 (-2.32, 4.56)		4.42 (-11.68, 20.51)	
p-value [3]		0.521		0.550	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	56	100	4	9	
Mean (StdDev)	40.85 (12.484)	43.36 (10.716)	36.51 (9.559)	34.37 (14.974)	
Median	39.27	44.79	33.75	39.27	
Min, Max	11.7, 55.8	17.2, 55.8	28.2, 50.3	11.7, 55.8	
C5D1 CFB					
n	54	96	4	9	
LS Mean (StdErr) [2]	2.94 (1.676)	5.07 (1.304)	4.69 (8.987)	3.04 (7.121)	
95% CI [2]	-0.37, 6.25	2.49, 7.64	-15.64, 25.02	-13.07, 19.15	
Difference (95% CI) in CFB [2]		2.13 (-1.49, 5.75)		-1.66 (-19.19, 15.88)	
p-value [3]		0.247		0.836	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	102	4	9	
Mean (StdDev)	41.72 (12.533)	42.30 (11.921)	24.09 (6.945)	32.53 (11.303)	
Median	44.79	44.79	22.71	28.23	
Min, Max	11.7, 55.8	11.7, 55.8	17.2, 33.8	17.2, 50.3	
C6D1 CFB					
n	52	98	4	9	
LS Mean (StdErr) [2]	3.53 (1.723)	3.37 (1.323)	-16.42 (9.971)	-6.48 (7.901)	
95% CI [2]	0.12, 6.93	0.76, 5.98	-38.97, 6.14	-24.36, 11.39	
Difference (95% CI) in CFB [2]		-0.16 (-3.88, 3.57)		9.93 (-9.52, 29.39)	
p-value [3]		0.933		0.278	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	54	102	4	9	
Mean (StdDev)	40.50 (12.670)	42.63 (11.602)	29.61 (11.378)	37.43 (13.519)	
Median	39.27	44.79	28.23	33.75	
Min, Max	11.7, 55.8	11.7, 55.8	17.2, 44.8	17.2, 55.8	
C7D1 CFB					
n	52	98	4	9	
LS Mean (StdErr) [2]	1.22 (1.482)	3.78 (1.119)	-4.69 (10.395)	2.48 (8.237)	
95% CI [2]	-1.71, 4.15	1.57, 5.99	-28.21, 18.82	-16.15, 21.12	
Difference (95% CI) in CFB [2]		2.56 (-0.59, 5.71)		7.17 (-13.11, 27.46)	
Hedges'G (95% CI) in CFB		0.23 (-0.10, 0.58)		0.28 (-0.98, 1.68)	
p-value [3]		0.110		0.444	
					0.191

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	60	110	4	9	
Mean (StdDev)	41.42 (9.654)	39.15 (9.670)	35.03 (3.042)	39.59 (11.380)	
Median	39.59	39.59	33.51	39.59	
Min, Max	21.3, 57.8	15.3, 57.8	33.5, 39.6	27.4, 63.9	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	61	111	4	8	
Mean (StdDev)	41.89 (10.604)	41.02 (10.341)	39.59 (4.967)	41.12 (11.146)	
Median	39.59	39.59	39.59	39.59	
Min, Max	21.3, 57.8	15.3, 57.8	33.5, 45.7	27.4, 57.8	
C2D1 CFB					
n	58	108	4	8	
LS Mean (StdErr) [2]	0.59 (1.031)	2.18 (0.808)	13.87 (6.072)	9.57 (4.787)	
95% CI [2]	-1.44, 2.63	0.58, 3.77	-0.14, 27.87	-1.47, 20.61	
Difference (95% CI) in CFB [2]		1.58 (-0.64, 3.81)		-4.29 (-16.47, 7.89)	
p-value [3]		0.162		0.440	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	59	102	4	8	
Mean (StdDev)	42.27 (10.431)	43.29 (10.833)	42.64 (6.083)	42.64 (14.173)	
Median	39.59	45.68	45.68	42.64	
Min, Max	15.3, 63.9	15.3, 57.8	33.5, 45.7	21.3, 63.9	
C3D1 CFB					
n	56	101	4	8	
LS Mean (StdErr) [2]	0.73 (1.213)	4.41 (0.936)	9.04 (10.085)	5.10 (7.951)	
95% CI [2]	-1.67, 3.12	2.56, 6.26	-14.22, 32.29	-13.24, 23.44	
Difference (95% CI) in CFB [2]		3.69 (1.07, 6.30)		-3.94 (-24.17, 16.30)	
p-value [3]		0.006		0.666	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	52	104	4	9	
Mean (StdDev)	42.52 (9.823)	44.22 (10.604)	36.55 (6.083)	38.24 (13.527)	
Median	39.59	45.68	33.51	39.59	
Min, Max	21.3, 63.9	21.3, 63.9	33.5, 45.7	15.3, 57.8	
C4D1 CFB					
n	49	102	4	9	
LS Mean (StdErr) [2]	1.90 (1.310)	5.35 (0.984)	5.47 (10.126)	1.22 (8.024)	
95% CI [2]	-0.69, 4.49	3.40, 7.29	-17.43, 28.38	-16.94, 19.37	
Difference (95% CI) in CFB [2]		3.45 (0.69, 6.21)		-4.26 (-24.02, 15.50)	
p-value [3]		0.015		0.638	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	56	100	4	9	
Mean (StdDev)	42.53 (11.126)	43.55 (10.280)	39.59 (4.967)	40.95 (13.180)	
Median	39.59	45.68	39.59	39.59	
Min, Max	21.3, 63.9	15.3, 63.9	33.5, 45.7	21.3, 63.9	
C5D1 CFB					
n	54	96	4	9	
LS Mean (StdErr) [2]	1.04 (1.361)	4.62 (1.059)	11.10 (8.390)	7.45 (6.648)	
95% CI [2]	-1.65, 3.73	2.53, 6.72	-7.88, 30.08	-7.59, 22.49	
Difference (95% CI) in CFB [2]		3.58 (0.64, 6.53)		-3.65 (-20.02, 12.72)	
p-value [3]		0.017		0.626	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	53	102	4	9	
Mean (StdDev)	43.38 (10.139)	42.99 (10.779)	33.51 (0.000)	39.59 (11.380)	
Median	39.59	45.68	33.51	39.59	
Min, Max	27.4, 63.9	15.3, 63.9	33.5, 33.5	27.4, 63.9	
C6D1 CFB					
n	51	98	4	9	
LS Mean (StdErr) [2]	1.46 (1.398)	4.25 (1.069)	-4.56 (6.480)	-1.52 (5.135)	
95% CI [2]	-1.30, 4.22	2.14, 6.36	-19.22, 10.10	-13.14, 10.09	
Difference (95% CI) in CFB [2]		2.79 (-0.24, 5.82)		3.04 (-9.60, 15.69)	
p-value [3]		0.070		0.600	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	54	102	4	9	
Mean (StdDev)	42.64 (10.814)	44.19 (11.657)	38.07 (9.125)	36.89 (13.640)	
Median	45.68	45.68	39.59	39.59	
Min, Max	15.3, 63.9	15.3, 63.9	27.4, 45.7	15.3, 63.9	
C7D1 CFB					
n	52	98	4	9	
LS Mean (StdErr) [2]	1.03 (1.561)	5.02 (1.178)	4.87 (10.148)	-0.61 (8.041)	
95% CI [2]	-2.05, 4.12	2.70, 7.35	-18.09, 27.82	-18.80, 17.58	
Difference (95% CI) in CFB [2]		3.99 (0.67, 7.31)		-5.47 (-25.28, 14.33)	
Hedges'G (95% CI) in CFB		0.34 (0.01, 0.69)		-0.22 (-1.60, 1.06)	
p-value [3]		0.019		0.547	
					0.111

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	60	109	4	9	
Mean (StdDev)	35.22 (10.472)	33.86 (10.633)	20.22 (7.592)	24.73 (5.145)	
Median	33.73	34.49	18.98	23.54	
Min, Max	15.6, 60.4	10.5, 61.8	13.8, 29.1	15.1, 31.3	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	61	111	4	8	
Mean (StdDev)	37.31 (11.015)	37.69 (11.980)	24.34 (2.854)	27.60 (9.936)	
Median	36.83	39.19	24.53	25.84	
Min, Max	16.5, 61.2	13.0, 58.5	20.9, 27.4	16.6, 47.3	
C2D1 CFB					
n	58	107	4	8	
LS Mean (StdErr) [2]	0.68 (1.022)	2.40 (0.808)	10.84 (3.782)	7.08 (2.982)	
95% CI [2]	-1.34, 2.70	0.80, 3.99	2.12, 19.56	0.20, 13.96	
Difference (95% CI) in CFB [2]		1.72 (-0.49, 3.92)		-3.76 (-11.35, 3.82)	
p-value [3]		0.126		0.286	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	59	102	4	8	
Mean (StdDev)	36.75 (9.974)	38.82 (11.974)	23.09 (6.109)	27.42 (6.522)	
Median	36.15	39.29	22.80	27.45	
Min, Max	15.1, 62.6	13.3, 61.4	17.7, 29.1	19.4, 40.1	
C3D1 CFB					
n	56	100	4	8	
LS Mean (StdErr) [2]	0.79 (1.049)	4.38 (0.817)	5.71 (1.812)	4.19 (1.429)	
95% CI [2]	-1.28, 2.87	2.77, 6.00	1.53, 9.89	0.90, 7.49	
Difference (95% CI) in CFB [2]		3.59 (1.33, 5.86)		-1.52 (-5.16, 2.11)	
p-value [3]		0.002		0.363	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	52	101	4	9	
Mean (StdDev)	37.14 (10.776)	39.05 (11.546)	26.11 (4.935)	29.67 (8.955)	
Median	36.55	40.27	25.83	25.92	
Min, Max	10.8, 61.5	12.8, 59.8	21.0, 31.8	18.0, 42.1	
C4D1 CFB					
n	49	98	4	9	
LS Mean (StdErr) [2]	0.75 (1.217)	3.91 (0.948)	8.96 (3.799)	7.09 (3.010)	
95% CI [2]	-1.66, 3.15	2.04, 5.78	0.37, 17.56	0.28, 13.90	
Difference (95% CI) in CFB [2]		3.16 (0.61, 5.72)		-1.87 (-9.28, 5.54)	
p-value [3]		0.016		0.582	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	56	100	4	9	
Mean (StdDev)	37.28 (10.927)	38.73 (12.304)	22.04 (7.077)	29.27 (7.193)	
Median	38.71	38.90	22.95	26.29	
Min, Max	15.9, 60.1	13.0, 64.3	13.5, 28.8	21.3, 38.8	
C5D1 CFB					
n	54	95	4	9	
LS Mean (StdErr) [2]	0.92 (1.150)	4.31 (0.902)	3.65 (2.495)	6.29 (1.977)	
95% CI [2]	-1.35, 3.20	2.53, 6.10	-1.99, 9.30	1.82, 10.76	
Difference (95% CI) in CFB [2]		3.39 (0.90, 5.88)		2.64 (-2.23, 7.51)	
p-value [3]		0.008		0.251	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	53	102	4	9	
Mean (StdDev)	36.17 (11.015)	41.18 (11.717)	22.93 (4.857)	27.19 (8.058)	
Median	36.03	43.14	22.18	25.11	
Min, Max	16.4, 58.8	17.3, 61.0	18.3, 29.0	18.0, 41.9	
C6D1 CFB					
n	51	97	4	9	
LS Mean (StdErr) [2]	-0.16 (1.178)	6.33 (0.908)	4.88 (4.145)	4.52 (3.285)	
95% CI [2]	-2.49, 2.17	4.53, 8.12	-4.50, 14.25	-2.92, 11.95	
Difference (95% CI) in CFB [2]		6.49 (3.94, 9.04)		-0.36 (-8.45, 7.73)	
p-value [3]		<0.0001		0.922	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	54	102	4	9	
Mean (StdDev)	38.42 (10.654)	40.28 (12.187)	21.68 (5.596)	29.73 (8.582)	
Median	38.15	39.62	22.33	27.88	
Min, Max	19.0, 63.2	12.5, 63.1	14.5, 27.6	18.0, 44.7	
C7D1 CFB					
n	52	97	4	9	
LS Mean (StdErr) [2]	0.64 (1.206)	4.27 (0.919)	6.44 (4.393)	9.41 (3.481)	
95% CI [2]	-1.75, 3.02	2.46, 6.09	-3.49, 16.38	1.54, 17.29	
Difference (95% CI) in CFB [2]		3.64 (1.07, 6.20)		2.97 (-5.61, 11.54)	
Hedges'G (95% CI) in CFB		0.41 (0.07, 0.75)		0.28 (-0.99, 1.67)	
p-value [3]		0.006		0.454	
					0.930

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	60	109	4	9	
Mean (StdDev)	40.87 (10.747)	39.94 (10.100)	36.66 (4.963)	39.77 (10.054)	
Median	39.29	39.52	36.21	38.10	
Min, Max	19.2, 58.7	13.2, 61.2	32.3, 41.9	27.3, 59.9	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	61	111	4	8	
Mean (StdDev)	42.37 (11.119)	41.76 (10.583)	40.36 (7.729)	43.14 (9.073)	
Median	42.37	41.67	42.21	42.70	
Min, Max	19.9, 64.4	19.0, 64.8	29.4, 47.6	28.5, 57.4	
C2D1 CFB					
n	58	107	4	8	
LS Mean (StdErr) [2]	1.95 (1.138)	2.66 (0.900)	6.19 (7.270)	4.95 (5.732)	
95% CI [2]	-0.30, 4.19	0.88, 4.43	-10.58, 22.95	-8.27, 18.16	
Difference (95% CI) in CFB [2]		0.71 (-1.75, 3.17)		-1.24 (-15.82, 13.34)	
p-value [3]		0.569		0.849	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	59	102	4	8	
Mean (StdDev)	43.49 (11.324)	42.91 (10.409)	42.81 (4.251)	43.46 (12.446)	
Median	44.18	44.84	41.97	47.11	
Min, Max	11.2, 63.3	13.8, 66.0	38.9, 48.4	22.7, 56.7	
C3D1 CFB					
n	56	100	4	8	
LS Mean (StdErr) [2]	2.94 (1.215)	3.74 (0.946)	9.15 (7.291)	6.07 (5.748)	
95% CI [2]	0.54, 5.34	1.87, 5.61	-7.66, 25.96	-7.18, 19.33	
Difference (95% CI) in CFB [2]		0.80 (-1.82, 3.42)		-3.08 (-17.70, 11.55)	
p-value [3]		0.547		0.641	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	52	101	4	9	
Mean (StdDev)	42.50 (10.273)	44.11 (10.882)	36.03 (5.838)	39.07 (11.934)	
Median	41.22	44.94	33.48	40.38	
Min, Max	22.0, 59.7	13.7, 63.9	32.4, 44.7	16.0, 58.4	
C4D1 CFB					
n	49	98	4	9	
LS Mean (StdErr) [2]	2.74 (1.407)	4.71 (1.096)	0.51 (9.023)	-2.02 (7.150)	
95% CI [2]	-0.04, 5.53	2.54, 6.87	-19.90, 20.92	-18.19, 14.16	
Difference (95% CI) in CFB [2]		1.96 (-0.99, 4.92)		-2.53 (-20.14, 15.08)	
p-value [3]		0.191		0.753	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	56	100	4	9	
Mean (StdDev)	42.83 (12.050)	44.31 (10.671)	39.72 (6.690)	42.26 (12.563)	
Median	43.12	45.37	37.59	44.18	
Min, Max	14.1, 61.6	19.5, 64.4	34.4, 49.3	21.3, 57.8	
C5D1 CFB					
n	54	95	4	9	
LS Mean (StdErr) [2]	1.98 (1.500)	4.74 (1.177)	7.83 (7.982)	5.01 (6.325)	
95% CI [2]	-0.99, 4.94	2.41, 7.06	-10.23, 25.89	-9.30, 19.32	
Difference (95% CI) in CFB [2]		2.76 (-0.49, 6.00)		-2.82 (-18.40, 12.76)	
p-value [3]		0.095		0.692	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	53	102	4	9	
Mean (StdDev)	43.97 (10.475)	43.15 (11.222)	30.39 (4.363)	39.90 (9.910)	
Median	42.30	43.26	30.75	42.90	
Min, Max	24.1, 61.4	12.1, 61.5	24.8, 35.2	26.2, 52.8	
C6D1 CFB					
n	51	97	4	9	
LS Mean (StdErr) [2]	2.67 (1.503)	3.31 (1.159)	-10.61 (6.204)	-4.30 (4.916)	
95% CI [2]	-0.30, 5.64	1.02, 5.60	-24.64, 3.43	-15.42, 6.82	
Difference (95% CI) in CFB [2]		0.64 (-2.62, 3.90)		6.30 (-5.80, 18.41)	
p-value [3]		0.699		0.269	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.7a
Change from Baseline of SF-12 by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=63)	Avapritinib 25 mg (N=114)	Placebo (N=4)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	54	102	4	9	
Mean (StdDev)	43.00 (11.465)	44.14 (11.321)	36.25 (11.732)	40.68 (14.415)	
Median	43.12	44.55	37.21	43.56	
Min, Max	12.1, 64.9	12.0, 63.3	21.4, 49.2	14.2, 60.7	
C7D1 CFB					
n	52	97	4	9	
LS Mean (StdErr) [2]	1.65 (1.447)	4.33 (1.102)	-0.31 (9.919)	-0.48 (7.860)	
95% CI [2]	-1.21, 4.51	2.15, 6.51	-22.75, 22.13	-18.26, 17.30	
Difference (95% CI) in CFB [2]		2.68 (-0.40, 5.76)		-0.17 (-19.53, 19.19)	
Hedges'G (95% CI) in CFB		0.25 (-0.09, 0.59)		-0.01 (-1.33, 1.31)	
p-value [3]		0.087		0.985	
					0.784

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	61	109	
Mean (StdDev)	48.10 (8.414)	36.32 (13.854)	37.62 (12.256)	36.75 (11.123)	
Median	48.10	35.48	39.69	39.69	
Min, Max	39.7, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	62	109	
Mean (StdDev)	48.10 (8.414)	38.84 (14.547)	39.55 (11.038)	39.99 (11.729)	
Median	48.10	35.48	39.69	39.69	
Min, Max	39.7, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C2D1 CFB					
n	3	10	59	106	
LS Mean (StdErr) [2]	0.90 (3.089)	4.16 (2.732)	1.10 (1.139)	2.14 (0.896)	
95% CI [2]	-6.09, 7.89	-2.02, 10.34	-1.15, 3.35	0.37, 3.91	
Difference (95% CI) in CFB [2]		3.26 (-4.72, 11.25)		1.03 (-1.41, 3.48)	
p-value [3]		0.380		0.405	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	10	60	100	
Mean (StdDev)	48.10 (8.414)	40.53 (15.078)	38.56 (10.213)	40.36 (11.820)	
Median	48.10	39.69	39.69	39.69	
Min, Max	39.7, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C3D1 CFB					
n	3	10	57	99	
LS Mean (StdErr) [2]	0.30 (4.211)	4.59 (3.724)	0.76 (1.171)	3.18 (0.909)	
95% CI [2]	-9.22, 9.83	-3.83, 13.02	-1.55, 3.08	1.38, 4.97	
Difference (95% CI) in CFB [2]		4.29 (-6.59, 15.18)		2.41 (-0.10, 4.93)	
p-value [3]		0.396		0.060	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	2	9	54	104	
Mean (StdDev)	48.10 (11.899)	41.56 (13.811)	38.91 (10.751)	40.58 (11.363)	
Median	48.10	39.69	39.69	39.69	
Min, Max	39.7, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C4D1 CFB					
n	2	9	51	102	
LS Mean (StdErr) [2]	5.65 (5.992)	6.53 (3.999)	1.99 (1.334)	4.10 (1.020)	
95% CI [2]	-8.52, 19.81	-2.93, 15.99	-0.65, 4.63	2.08, 6.12	
Difference (95% CI) in CFB [2]		0.89 (-14.03, 15.81)		2.11 (-0.70, 4.92)	
p-value [3]		0.892		0.139	

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Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	8	57	101	
Mean (StdDev)	45.29 (4.858)	39.69 (14.917)	39.54 (12.469)	40.93 (11.499)	
Median	48.10	35.48	39.69	39.69	
Min, Max	39.7, 48.1	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C5D1 CFB					
n	3	8	55	97	
LS Mean (StdErr) [2]	-2.57 (5.217)	3.04 (4.607)	1.38 (1.308)	4.51 (1.019)	
95% CI [2]	-14.91, 9.77	-7.86, 13.93	-1.21, 3.96	2.49, 6.52	
Difference (95% CI) in CFB [2]		5.61 (-8.57, 19.79)		3.13 (0.33, 5.93)	
p-value [3]		0.381		0.029	

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Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	55	102	
Mean (StdDev)	48.10 (8.414)	42.49 (14.574)	38.16 (11.229)	42.08 (12.097)	
Median	48.10	39.69	39.69	39.69	
Min, Max	39.7, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C6D1 CFB					
n	3	9	53	98	
LS Mean (StdErr) [2]	0.15 (4.391)	4.70 (3.881)	0.34 (1.340)	5.00 (1.031)	
95% CI [2]	-9.98, 10.27	-4.25, 13.65	-2.30, 2.99	2.97, 7.04	
Difference (95% CI) in CFB [2]		4.55 (-7.05, 16.15)		4.66 (1.79, 7.53)	
p-value [3]		0.392		0.002	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	8	55	103	
Mean (StdDev)	45.29 (9.716)	42.84 (15.539)	39.07 (11.318)	41.48 (11.879)	
Median	39.69	48.10	39.69	39.69	
Min, Max	39.7, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C7D1 CFB					
n	3	8	53	99	
LS Mean (StdErr) [2]	-3.10 (4.983)	4.62 (4.400)	0.22 (1.441)	3.78 (1.091)	
95% CI [2]	-14.88, 8.69	-5.79, 15.02	-2.63, 3.07	1.62, 5.93	
Difference (95% CI) in CFB [2]		7.71 (-5.83, 21.26)		3.56 (0.53, 6.59)	
Hedges'G (95% CI) in CFB		0.60 (-0.79, 2.34)		0.33 (-0.00, 0.67)	
p-value [3]		0.220		0.022	
					0.549

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	61	109	
Mean (StdDev)	42.00 (10.368)	30.92 (10.105)	34.29 (7.620)	34.47 (8.321)	
Median	47.98	30.03	34.51	34.51	
Min, Max	30.0, 48.0	21.0, 48.0	21.0, 52.5	21.0, 57.0	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	62	109	
Mean (StdDev)	39.00 (16.187)	35.41 (11.357)	36.18 (9.312)	36.90 (9.993)	
Median	43.49	34.51	34.51	34.51	
Min, Max	21.0, 52.5	21.0, 52.5	21.0, 57.0	21.0, 57.0	
C2D1 CFB					
n	3	10	59	106	
LS Mean (StdErr) [2]	-4.65 (6.235)	1.40 (5.515)	1.22 (1.041)	1.89 (0.819)	
95% CI [2]	-18.75, 9.46	-11.08, 13.87	-0.83, 3.28	0.27, 3.51	
Difference (95% CI) in CFB [2]		6.05 (-10.07, 22.17)		0.67 (-1.57, 2.90)	
p-value [3]		0.418		0.556	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	10	60	100	
Mean (StdDev)	40.50 (11.298)	37.66 (10.379)	36.46 (9.793)	38.69 (10.333)	
Median	39.00	36.76	34.51	39.00	
Min, Max	30.0, 52.5	21.0, 48.0	21.0, 57.0	21.0, 57.0	
C3D1 CFB					
n	3	10	57	99	
LS Mean (StdErr) [2]	-3.21 (4.628)	3.57 (4.094)	1.85 (1.151)	4.24 (0.893)	
95% CI [2]	-13.68, 7.26	-5.69, 12.83	-0.43, 4.12	2.47, 6.00	
Difference (95% CI) in CFB [2]		6.78 (-5.19, 18.75)		2.39 (-0.08, 4.86)	
p-value [3]		0.232		0.058	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	2	9	54	102	
Mean (StdDev)	41.25 (9.523)	40.00 (11.830)	36.26 (10.111)	39.40 (10.267)	
Median	41.25	43.49	36.76	39.00	
Min, Max	34.5, 48.0	21.0, 52.5	21.0, 57.0	21.0, 57.0	
C4D1 CFB					
n	2	9	51	100	
LS Mean (StdErr) [2]	3.84 (4.701)	6.20 (3.138)	1.51 (1.221)	4.53 (0.943)	
95% CI [2]	-7.28, 14.96	-1.22, 13.62	-0.90, 3.92	2.67, 6.40	
Difference (95% CI) in CFB [2]		2.36 (-9.34, 14.07)		3.02 (0.45, 5.59)	
p-value [3]		0.648		0.021	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	8	57	101	
Mean (StdDev)	42.00 (6.858)	37.32 (11.239)	36.33 (9.250)	38.87 (10.048)	
Median	43.49	34.51	39.00	39.00	
Min, Max	34.5, 48.0	25.5, 52.5	21.0, 57.0	21.0, 57.0	
C5D1 CFB					
n	3	8	55	97	
LS Mean (StdErr) [2]	-0.81 (3.707)	4.43 (3.274)	1.75 (1.180)	4.72 (0.919)	
95% CI [2]	-9.58, 7.96	-3.31, 12.17	-0.58, 4.08	2.91, 6.54	
Difference (95% CI) in CFB [2]		5.24 (-4.84, 15.31)		2.97 (0.45, 5.50)	
p-value [3]		0.259		0.021	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	55	102	
Mean (StdDev)	37.51 (9.345)	39.50 (11.759)	35.49 (9.952)	40.46 (10.517)	
Median	34.51	39.00	34.51	39.00	
Min, Max	30.0, 48.0	21.0, 52.5	21.0, 57.0	21.0, 57.0	
C6D1 CFB					
n	3	9	53	98	
LS Mean (StdErr) [2]	-6.76 (5.677)	2.90 (5.018)	0.82 (1.292)	5.72 (0.994)	
95% CI [2]	-19.85, 6.33	-8.67, 14.48	-1.74, 3.37	3.75, 7.68	
Difference (95% CI) in CFB [2]		9.67 (-5.33, 24.66)		4.90 (2.13, 7.67)	
p-value [3]		0.176		<0.001	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	8	55	103	
Mean (StdDev)	40.50 (6.858)	42.37 (11.191)	37.62 (10.752)	40.09 (10.714)	
Median	39.00	45.74	39.00	39.00	
Min, Max	34.5, 48.0	25.5, 57.0	21.0, 57.0	21.0, 57.0	
C7D1 CFB					
n	3	8	53	99	
LS Mean (StdErr) [2]	-2.46 (4.987)	6.89 (4.404)	2.16 (1.302)	5.10 (0.986)	
95% CI [2]	-14.25, 9.33	-3.52, 17.30	-0.41, 4.73	3.15, 7.04	
Difference (95% CI) in CFB [2]		9.35 (-4.20, 22.91)		2.94 (0.20, 5.67)	
Hedges'G (95% CI) in CFB		0.73 (-0.65, 2.52)		0.30 (-0.03, 0.64)	
p-value [3]		0.147		0.036	
					0.197

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	61	108	
Mean (StdDev)	39.69 (11.859)	27.03 (11.303)	32.06 (10.994)	31.80 (11.517)	
Median	46.54	26.00	26.00	26.00	
Min, Max	26.0, 46.5	15.7, 46.5	15.7, 56.8	15.7, 56.8	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	62	109	
Mean (StdDev)	49.96 (11.859)	32.16 (13.864)	35.11 (11.174)	38.44 (12.428)	
Median	56.81	31.13	36.27	36.27	
Min, Max	36.3, 56.8	15.7, 46.5	15.7, 56.8	15.7, 56.8	
C2D1 CFB					
n	3	10	59	105	
LS Mean (StdErr) [2]	9.54 (6.049)	3.46 (5.351)	1.24 (1.523)	4.74 (1.210)	
95% CI [2]	-4.15, 23.22	-8.65, 15.56	-1.77, 4.25	2.35, 7.13	
Difference (95% CI) in CFB [2]		-6.08 (-21.72, 9.56)		3.50 (0.24, 6.77)	
p-value [3]		0.402		0.036	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	10	60	100	
Mean (StdDev)	46.54 (17.789)	34.21 (13.522)	35.93 (10.691)	39.25 (11.886)	
Median	56.81	36.27	36.27	36.27	
Min, Max	26.0, 56.8	15.7, 46.5	15.7, 56.8	15.7, 56.8	
C3D1 CFB					
n	3	10	57	98	
LS Mean (StdErr) [2]	7.34 (6.064)	7.96 (5.364)	3.33 (1.412)	7.50 (1.106)	
95% CI [2]	-6.38, 21.05	-4.17, 20.10	0.54, 6.12	5.32, 9.68	
Difference (95% CI) in CFB [2]		0.63 (-15.05, 16.31)		4.17 (1.13, 7.20)	
p-value [3]		0.930		0.007	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	2	9	54	103	
Mean (StdDev)	41.40 (7.262)	37.41 (11.982)	35.89 (11.102)	38.46 (12.754)	
Median	41.40	46.54	36.27	36.27	
Min, Max	36.3, 46.5	15.7, 46.5	15.7, 56.8	15.7, 56.8	
C4D1 CFB					
n	2	9	51	100	
LS Mean (StdErr) [2]	11.89 (5.808)	9.73 (3.876)	1.77 (1.628)	5.04 (1.279)	
95% CI [2]	-1.84, 25.62	0.56, 18.90	-1.45, 4.99	2.51, 7.57	
Difference (95% CI) in CFB [2]		-2.16 (-16.62, 12.30)		3.27 (-0.14, 6.68)	
p-value [3]		0.734		0.060	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	8	57	101	
Mean (StdDev)	46.54 (10.270)	34.98 (13.929)	35.19 (12.227)	38.51 (13.121)	
Median	46.54	41.40	36.27	36.27	
Min, Max	36.3, 56.8	15.7, 46.5	15.7, 56.8	15.7, 56.8	
C5D1 CFB					
n	3	8	55	96	
LS Mean (StdErr) [2]	6.99 (6.140)	5.28 (5.422)	1.26 (1.597)	5.70 (1.255)	
95% CI [2]	-7.53, 21.51	-7.54, 18.10	-1.90, 4.42	3.22, 8.18	
Difference (95% CI) in CFB [2]		-1.71 (-18.40, 14.98)		4.44 (1.02, 7.86)	
p-value [3]		0.815		0.011	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	54	102	
Mean (StdDev)	49.96 (11.859)	38.55 (16.058)	34.18 (12.520)	39.59 (12.695)	
Median	56.81	46.54	36.27	46.54	
Min, Max	36.3, 56.8	15.7, 56.8	15.7, 56.8	15.7, 56.8	
C6D1 CFB					
n	3	9	52	97	
LS Mean (StdErr) [2]	9.91 (9.227)	9.06 (8.156)	0.54 (1.554)	6.91 (1.202)	
95% CI [2]	-11.37, 31.19	-9.75, 27.87	-2.53, 3.61	4.53, 9.28	
Difference (95% CI) in CFB [2]		-0.85 (-25.22, 23.53)		6.36 (3.03, 9.70)	
p-value [3]		0.938		<0.001	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	8	55	103	
Mean (StdDev)	46.54 (10.270)	42.69 (14.460)	36.83 (11.426)	38.76 (13.527)	
Median	46.54	46.54	36.27	36.27	
Min, Max	36.3, 56.8	15.7, 56.8	15.7, 56.8	15.7, 56.8	
C7D1 CFB					
n	3	8	53	98	
LS Mean (StdErr) [2]	7.13 (7.960)	13.98 (7.030)	1.16 (1.541)	4.06 (1.177)	
95% CI [2]	-11.69, 25.96	-2.64, 30.60	-1.88, 4.21	1.74, 6.39	
Difference (95% CI) in CFB [2]		6.85 (-14.79, 28.48)		2.90 (-0.34, 6.14)	
Hedges'G (95% CI) in CFB		0.33 (-1.11, 1.97)		0.25 (-0.08, 0.59)	
p-value [3]		0.479		0.079	
					0.659

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	61	109	
Mean (StdDev)	39.96 (8.586)	29.41 (7.014)	33.70 (10.673)	33.69 (9.693)	
Median	44.92	30.05	30.05	30.05	
Min, Max	30.0, 44.9	19.4, 44.9	19.4, 61.9	19.4, 55.5	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	62	109	
Mean (StdDev)	39.96 (8.586)	30.90 (8.569)	35.94 (11.172)	35.50 (10.703)	
Median	44.92	30.05	30.05	30.05	
Min, Max	30.0, 44.9	19.4, 44.9	19.4, 55.5	19.4, 55.5	
C2D1 CFB					
n	3	10	59	106	
LS Mean (StdErr) [2]	1.59 (3.589)	5.24 (3.175)	1.66 (1.293)	1.81 (1.018)	
95% CI [2]	-6.53, 9.71	-1.95, 12.42	-0.89, 4.22	-0.20, 3.82	
Difference (95% CI) in CFB [2]		3.64 (-5.64, 12.92)		0.14 (-2.63, 2.92)	
p-value [3]		0.398		0.919	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	10	60	100	
Mean (StdDev)	39.96 (8.586)	36.42 (9.501)	34.54 (10.126)	36.78 (11.247)	
Median	44.92	37.48	30.05	30.05	
Min, Max	30.0, 44.9	19.4, 44.9	19.4, 55.5	19.4, 61.9	
C3D1 CFB					
n	3	10	57	99	
LS Mean (StdErr) [2]	-0.38 (4.107)	6.64 (3.633)	0.04 (1.409)	3.28 (1.094)	
95% CI [2]	-9.67, 8.91	-1.57, 14.86	-2.74, 2.82	1.12, 5.44	
Difference (95% CI) in CFB [2]		7.02 (-3.59, 17.64)		3.24 (0.21, 6.26)	
p-value [3]		0.169		0.036	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	2	9	54	104	
Mean (StdDev)	37.48 (10.516)	39.96 (11.091)	35.83 (10.954)	36.48 (10.980)	
Median	37.48	44.92	30.05	30.05	
Min, Max	30.0, 44.9	19.4, 55.5	19.4, 61.9	19.4, 55.5	
C4D1 CFB					
n	2	9	51	102	
LS Mean (StdErr) [2]	-0.48 (8.555)	13.61 (5.710)	0.73 (1.485)	2.17 (1.136)	
95% CI [2]	-20.70, 19.75	0.11, 27.12	-2.21, 3.66	-0.07, 4.42	
Difference (95% CI) in CFB [2]		14.09 (-7.21, 35.39)		1.45 (-1.68, 4.57)	
p-value [3]		0.162		0.362	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	8	57	101	
Mean (StdDev)	39.96 (8.586)	39.34 (11.689)	35.79 (10.322)	37.13 (10.738)	
Median	44.92	44.92	30.05	44.92	
Min, Max	30.0, 44.9	19.4, 55.5	19.4, 61.9	19.4, 55.5	
C5D1 CFB					
n	3	8	55	97	
LS Mean (StdErr) [2]	2.24 (6.309)	13.57 (5.572)	1.58 (1.458)	3.34 (1.135)	
95% CI [2]	-12.68, 17.16	0.40, 26.75	-1.30, 4.46	1.10, 5.59	
Difference (95% CI) in CFB [2]		11.33 (-5.82, 28.48)		1.76 (-1.36, 4.88)	
p-value [3]		0.162		0.267	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	55	102	
Mean (StdDev)	39.96 (8.586)	38.78 (12.723)	35.69 (11.545)	38.06 (10.948)	
Median	44.92	44.92	30.05	44.92	
Min, Max	30.0, 44.9	19.4, 55.5	19.4, 61.9	19.4, 55.5	
C6D1 CFB					
n	3	9	53	98	
LS Mean (StdErr) [2]	2.35 (6.258)	13.50 (5.531)	1.17 (1.467)	4.32 (1.129)	
95% CI [2]	-12.08, 16.78	0.74, 26.25	-1.73, 4.07	2.09, 6.55	
Difference (95% CI) in CFB [2]		11.15 (-5.39, 27.68)		3.15 (0.01, 6.30)	
p-value [3]		0.159		0.049	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	8	55	103	
Mean (StdDev)	39.96 (8.586)	42.53 (8.531)	36.15 (11.168)	38.38 (11.257)	
Median	44.92	44.92	30.05	44.92	
Min, Max	30.0, 44.9	30.0, 55.5	19.4, 55.5	19.4, 55.5	
C7D1 CFB					
n	3	8	53	99	
LS Mean (StdErr) [2]	1.00 (4.522)	14.46 (3.993)	0.31 (1.534)	3.64 (1.162)	
95% CI [2]	-9.69, 11.70	5.02, 23.90	-2.72, 3.34	1.35, 5.94	
Difference (95% CI) in CFB [2]		13.46 (1.17, 25.75)		3.34 (0.11, 6.56)	
Hedges'G (95% CI) in CFB		1.16 (-0.18, 3.15)		0.29 (-0.04, 0.63)	
p-value [3]		0.036		0.043	
					0.222

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	61	109	
Mean (StdDev)	44.75 (11.263)	34.35 (6.820)	39.05 (8.956)	37.09 (8.260)	
Median	38.25	33.37	38.25	38.25	
Min, Max	38.2, 57.8	28.5, 48.0	28.5, 57.8	28.5, 57.8	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	62	109	
Mean (StdDev)	44.75 (5.631)	40.20 (11.990)	40.29 (9.200)	38.97 (9.358)	
Median	48.00	38.25	38.25	38.25	
Min, Max	38.2, 48.0	28.5, 57.8	28.5, 67.5	28.5, 57.8	
C2D1 CFB					
n	3	10	59	106	
LS Mean (StdErr) [2]	0.35 (6.389)	6.72 (5.651)	1.21 (1.164)	2.40 (0.916)	
95% CI [2]	-14.10, 14.80	-6.06, 19.50	-1.09, 3.51	0.59, 4.21	
Difference (95% CI) in CFB [2]		6.37 (-10.15, 22.89)		1.19 (-1.31, 3.69)	
p-value [3]		0.406		0.349	

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Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	10	60	100	
Mean (StdDev)	38.25 (9.754)	42.15 (11.449)	41.66 (9.807)	40.00 (9.643)	
Median	38.25	43.13	38.25	38.25	
Min, Max	28.5, 48.0	28.5, 57.8	28.5, 67.5	28.5, 57.8	
C3D1 CFB					
n	3	10	57	99	
LS Mean (StdErr) [2]	-4.88 (6.897)	11.84 (6.100)	3.30 (1.145)	3.54 (0.888)	
95% CI [2]	-20.48, 10.73	-1.96, 25.64	1.04, 5.56	1.78, 5.30	
Difference (95% CI) in CFB [2]		16.72 (-1.11, 34.55)		0.24 (-2.22, 2.70)	
p-value [3]		0.063		0.847	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	2	9	54	104	
Mean (StdDev)	48.00 (0.000)	42.58 (12.056)	39.87 (8.631)	40.22 (10.115)	
Median	48.00	48.00	38.25	38.25	
Min, Max	48.0, 48.0	28.5, 57.8	28.5, 57.8	28.5, 57.8	
C4D1 CFB					
n	2	9	51	102	
LS Mean (StdErr) [2]	17.20 (5.685)	10.52 (3.795)	0.73 (1.453)	2.49 (1.111)	
95% CI [2]	3.75, 30.64	1.55, 19.50	-2.14, 3.60	0.30, 4.69	
Difference (95% CI) in CFB [2]		-6.67 (-20.83, 7.48)		1.76 (-1.30, 4.82)	
p-value [3]		0.302		0.257	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	8	57	101	
Mean (StdDev)	44.75 (5.631)	41.91 (11.585)	39.96 (9.421)	40.57 (9.961)	
Median	48.00	48.00	38.25	38.25	
Min, Max	38.2, 48.0	28.5, 57.8	28.5, 57.8	28.5, 67.5	
C5D1 CFB					
n	3	8	55	97	
LS Mean (StdErr) [2]	0.95 (5.210)	9.08 (4.601)	0.97 (1.465)	3.62 (1.141)	
95% CI [2]	-11.37, 13.27	-1.80, 19.96	-1.92, 3.87	1.36, 5.87	
Difference (95% CI) in CFB [2]		8.13 (-6.03, 22.29)		2.64 (-0.49, 5.78)	
p-value [3]		0.217		0.098	

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Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	55	102	
Mean (StdDev)	41.50 (5.631)	43.67 (12.056)	38.78 (9.084)	41.79 (10.160)	
Median	38.25	38.25	38.25	38.25	
Min, Max	38.2, 48.0	28.5, 57.8	28.5, 57.8	28.5, 67.5	
C6D1 CFB					
n	3	9	53	98	
LS Mean (StdErr) [2]	-3.44 (4.868)	8.03 (4.303)	0.19 (1.404)	4.68 (1.080)	
95% CI [2]	-14.67, 7.78	-1.89, 17.96	-2.58, 2.97	2.54, 6.81	
Difference (95% CI) in CFB [2]		11.48 (-1.39, 24.34)		4.49 (1.48, 7.50)	
p-value [3]		0.074		0.004	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	8	55	103	
Mean (StdDev)	44.75 (5.631)	45.56 (12.502)	41.09 (10.730)	41.00 (10.259)	
Median	48.00	48.00	38.25	38.25	
Min, Max	38.2, 48.0	28.5, 57.8	28.5, 67.5	28.5, 67.5	
C7D1 CFB					
n	3	8	53	99	
LS Mean (StdErr) [2]	1.15 (6.205)	11.72 (5.480)	2.13 (1.401)	3.33 (1.061)	
95% CI [2]	-13.52, 15.83	-1.24, 24.68	-0.64, 4.90	1.24, 5.43	
Difference (95% CI) in CFB [2]		10.57 (-6.30, 27.43)		1.20 (-1.75, 4.15)	
Hedges'G (95% CI) in CFB		0.66 (-0.72, 2.43)		0.11 (-0.22, 0.45)	
p-value [3]		0.182		0.422	
					0.166

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	61	109	
Mean (StdDev)	39.59 (5.724)	34.30 (12.187)	36.61 (12.002)	36.92 (10.561)	
Median	36.29	36.29	36.29	36.29	
Min, Max	36.3, 46.2	16.5, 56.1	16.5, 56.1	16.5, 56.1	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	62	109	
Mean (StdDev)	36.29 (0.000)	35.29 (11.869)	39.96 (10.806)	40.74 (11.327)	
Median	36.29	36.29	36.29	36.29	
Min, Max	36.3, 36.3	16.5, 56.1	16.5, 56.1	16.5, 56.1	
C2D1 CFB					
n	3	10	59	106	
LS Mean (StdErr) [2]	-2.48 (4.293)	3.19 (3.797)	2.68 (1.498)	3.50 (1.179)	
95% CI [2]	-12.19, 7.23	-5.40, 11.78	-0.27, 5.64	1.17, 5.83	
Difference (95% CI) in CFB [2]		5.67 (-5.43, 16.76)		0.81 (-2.40, 4.03)	
p-value [3]		0.278		0.617	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	10	60	100	
Mean (StdDev)	39.59 (5.724)	38.27 (14.630)	40.91 (11.467)	40.45 (11.550)	
Median	36.29	41.24	36.29	36.29	
Min, Max	36.3, 46.2	16.5, 56.1	16.5, 56.1	16.5, 56.1	
C3D1 CFB					
n	3	10	57	99	
LS Mean (StdErr) [2]	1.06 (5.757)	6.32 (5.092)	4.37 (1.475)	3.59 (1.144)	
95% CI [2]	-11.96, 14.08	-5.20, 17.84	1.46, 7.29	1.33, 5.85	
Difference (95% CI) in CFB [2]		5.26 (-9.62, 20.14)		-0.79 (-3.95, 2.38)	
p-value [3]		0.445		0.624	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	2	9	54	104	
Mean (StdDev)	41.24 (7.010)	39.59 (11.084)	39.41 (11.201)	40.48 (12.563)	
Median	41.24	46.20	36.29	41.24	
Min, Max	36.3, 46.2	26.4, 56.1	16.5, 56.1	16.5, 56.1	
C4D1 CFB					
n	2	9	51	102	
LS Mean (StdErr) [2]	9.39 (11.124)	6.78 (7.425)	2.09 (1.679)	3.60 (1.284)	
95% CI [2]	-16.91, 35.70	-10.77, 24.34	-1.23, 5.40	1.06, 6.13	
Difference (95% CI) in CFB [2]		-2.61 (-30.31, 25.09)		1.51 (-2.02, 5.04)	
p-value [3]		0.830		0.399	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	8	57	101	
Mean (StdDev)	42.90 (11.448)	43.72 (11.550)	39.24 (11.844)	42.27 (12.309)	
Median	36.29	41.24	36.29	46.20	
Min, Max	36.3, 56.1	26.4, 56.1	16.5, 56.1	16.5, 56.1	
C5D1 CFB					
n	3	8	55	97	
LS Mean (StdErr) [2]	4.54 (6.313)	9.50 (5.575)	1.82 (1.739)	5.58 (1.354)	
95% CI [2]	-10.38, 19.47	-3.68, 22.68	-1.61, 5.26	2.91, 8.26	
Difference (95% CI) in CFB [2]		4.96 (-12.20, 22.12)		3.76 (0.04, 7.48)	
p-value [3]		0.516		0.048	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	55	102	
Mean (StdDev)	36.29 (0.000)	41.79 (12.254)	39.17 (11.865)	41.83 (12.208)	
Median	36.29	46.20	36.29	46.20	
Min, Max	36.3, 36.3	16.5, 56.1	16.5, 56.1	16.5, 56.1	
C6D1 CFB					
n	3	9	53	98	
LS Mean (StdErr) [2]	-1.92 (7.566)	8.46 (6.688)	1.96 (1.783)	4.74 (1.372)	
95% CI [2]	-19.37, 15.52	-6.97, 23.88	-1.56, 5.49	2.03, 7.45	
Difference (95% CI) in CFB [2]		10.38 (-9.61, 30.37)		2.77 (-1.05, 6.60)	
p-value [3]		0.265		0.154	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	8	55	103	
Mean (StdDev)	36.29 (0.000)	48.68 (7.010)	40.43 (12.171)	42.16 (12.832)	
Median	36.29	46.20	36.29	46.20	
Min, Max	36.3, 36.3	36.3, 56.1	16.5, 56.1	16.5, 56.1	
C7D1 CFB					
n	3	8	53	99	
LS Mean (StdErr) [2]	-3.37 (7.345)	12.32 (6.486)	2.06 (1.738)	4.50 (1.316)	
95% CI [2]	-20.74, 14.00	-3.01, 27.66	-1.37, 5.50	1.90, 7.10	
Difference (95% CI) in CFB [2]		15.70 (-4.27, 35.66)		2.43 (-1.22, 6.09)	
Hedges'G (95% CI) in CFB		0.83 (-0.53, 2.67)		0.19 (-0.15, 0.53)	
p-value [3]		0.105		0.191	
					0.088

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	61	109	
Mean (StdDev)	37.43 (16.861)	37.62 (11.053)	37.28 (11.838)	37.60 (11.815)	
Median	33.75	36.51	33.75	39.27	
Min, Max	22.7, 55.8	22.7, 55.8	11.7, 55.8	11.7, 55.8	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	62	109	
Mean (StdDev)	39.27 (9.559)	39.27 (12.477)	39.98 (11.589)	40.99 (11.939)	
Median	33.75	42.03	39.27	44.79	
Min, Max	33.8, 50.3	22.7, 55.8	17.2, 55.8	11.7, 55.8	
C2D1 CFB					
n	3	10	59	106	
LS Mean (StdErr) [2]	2.37 (5.458)	3.04 (4.827)	3.19 (1.374)	3.74 (1.082)	
95% CI [2]	-9.98, 14.71	-7.88, 13.96	0.47, 5.90	1.60, 5.87	
Difference (95% CI) in CFB [2]		0.68 (-13.43, 14.79)		0.55 (-2.40, 3.50)	
p-value [3]		0.916		0.714	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	10	60	100	
Mean (StdDev)	39.27 (14.602)	43.13 (14.022)	40.65 (12.512)	41.15 (11.954)	
Median	33.75	47.55	44.79	44.79	
Min, Max	28.2, 55.8	17.2, 55.8	11.7, 55.8	11.7, 55.8	
C3D1 CFB					
n	3	10	57	99	
LS Mean (StdErr) [2]	3.35 (7.184)	8.64 (6.354)	3.54 (1.466)	4.15 (1.138)	
95% CI [2]	-12.90, 19.60	-5.73, 23.02	0.65, 6.44	1.90, 6.40	
Difference (95% CI) in CFB [2]		5.29 (-13.28, 23.87)		0.61 (-2.54, 3.76)	
p-value [3]		0.535		0.702	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	2	9	54	103	
Mean (StdDev)	33.75 (0.000)	42.34 (10.727)	39.37 (12.387)	42.16 (12.361)	
Median	33.75	44.79	39.27	44.79	
Min, Max	33.8, 33.8	22.7, 55.8	17.2, 55.8	11.7, 55.8	
C4D1 CFB					
n	2	9	51	101	
LS Mean (StdErr) [2]	11.98 (8.560)	7.04 (5.714)	2.55 (1.674)	4.58 (1.281)	
95% CI [2]	-8.26, 32.22	-6.47, 20.55	-0.76, 5.86	2.05, 7.11	
Difference (95% CI) in CFB [2]		-4.94 (-26.25, 16.38)		2.03 (-1.50, 5.55)	
p-value [3]		0.601		0.257	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	8	57	101	
Mean (StdDev)	41.11 (12.745)	44.10 (9.977)	40.53 (12.385)	42.50 (11.451)	
Median	33.75	44.79	39.27	44.79	
Min, Max	33.8, 55.8	22.7, 55.8	11.7, 55.8	11.7, 55.8	
C5D1 CFB					
n	3	8	55	97	
LS Mean (StdErr) [2]	2.68 (7.694)	3.60 (6.794)	3.05 (1.687)	4.94 (1.314)	
95% CI [2]	-15.51, 20.88	-12.46, 19.67	-0.28, 6.38	2.34, 7.53	
Difference (95% CI) in CFB [2]		0.92 (-19.99, 21.83)		1.88 (-1.73, 5.50)	
p-value [3]		0.920		0.304	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	55	102	
Mean (StdDev)	39.27 (9.559)	44.18 (12.779)	40.58 (13.222)	41.27 (12.101)	
Median	33.75	50.31	44.79	44.79	
Min, Max	33.8, 50.3	22.7, 55.8	11.7, 55.8	11.7, 55.8	
C6D1 CFB					
n	3	9	53	98	
LS Mean (StdErr) [2]	3.60 (9.585)	9.25 (8.472)	2.38 (1.756)	2.73 (1.351)	
95% CI [2]	-18.50, 25.71	-10.28, 28.79	-1.09, 5.85	0.06, 5.40	
Difference (95% CI) in CFB [2]		5.65 (-19.67, 30.97)		0.36 (-3.41, 4.12)	
p-value [3]		0.621		0.852	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	8	55	103	
Mean (StdDev)	37.43 (6.373)	42.72 (8.311)	39.87 (13.081)	42.16 (12.043)	
Median	33.75	44.79	39.27	44.79	
Min, Max	33.8, 44.8	28.2, 55.8	11.7, 55.8	11.7, 55.8	
C7D1 CFB					
n	3	8	53	99	
LS Mean (StdErr) [2]	-0.92 (4.802)	4.60 (4.240)	0.67 (1.590)	3.64 (1.204)	
95% CI [2]	-12.27, 10.43	-5.43, 14.63	-2.47, 3.82	1.27, 6.02	
Difference (95% CI) in CFB [2]		5.52 (-7.53, 18.57)		2.97 (-0.37, 6.31)	
Hedges'G (95% CI) in CFB		0.45 (-0.98, 2.13)		0.25 (-0.08, 0.59)	
p-value [3]		0.351		0.081	
					0.722

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	61	109	
Mean (StdDev)	43.65 (12.663)	37.16 (8.698)	40.89 (9.431)	39.37 (9.862)	
Median	39.59	39.59	39.59	39.59	
Min, Max	33.5, 57.8	21.3, 51.8	21.3, 57.8	15.3, 63.9	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	62	109	
Mean (StdDev)	49.73 (9.292)	40.81 (11.754)	41.36 (10.297)	41.05 (10.269)	
Median	51.76	42.64	39.59	39.59	
Min, Max	39.6, 57.8	15.3, 57.8	21.3, 57.8	15.3, 57.8	
C2D1 CFB					
n	3	10	59	106	
LS Mean (StdErr) [2]	6.30 (3.984)	4.19 (3.524)	0.81 (1.063)	2.23 (0.837)	
95% CI [2]	-2.71, 15.31	-3.78, 12.16	-1.29, 2.91	0.58, 3.88	
Difference (95% CI) in CFB [2]		-2.11 (-12.41, 8.19)		1.42 (-0.86, 3.70)	
p-value [3]		0.654		0.220	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	10	60	100	
Mean (StdDev)	43.65 (7.024)	43.24 (11.542)	42.23 (10.348)	43.24 (11.039)	
Median	39.59	45.68	39.59	45.68	
Min, Max	39.6, 51.8	21.3, 57.8	15.3, 63.9	15.3, 63.9	
C3D1 CFB					
n	3	10	57	99	
LS Mean (StdErr) [2]	0.87 (4.858)	8.07 (4.297)	1.25 (1.285)	4.20 (0.997)	
95% CI [2]	-10.12, 11.86	-1.65, 17.79	-1.29, 3.79	2.23, 6.17	
Difference (95% CI) in CFB [2]		7.20 (-5.36, 19.76)		2.95 (0.19, 5.71)	
p-value [3]		0.227		0.037	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	2	9	54	104	
Mean (StdDev)	36.55 (4.301)	45.00 (10.290)	42.30 (9.792)	43.63 (11.007)	
Median	36.55	45.68	39.59	45.68	
Min, Max	33.5, 39.6	27.4, 57.8	21.3, 63.9	15.3, 63.9	
C4D1 CFB					
n	2	9	51	102	
LS Mean (StdErr) [2]	4.64 (6.378)	12.65 (4.257)	1.88 (1.378)	4.64 (1.054)	
95% CI [2]	-10.44, 19.72	2.58, 22.71	-0.84, 4.60	2.55, 6.72	
Difference (95% CI) in CFB [2]		8.00 (-7.88, 23.88)		2.76 (-0.14, 5.65)	
p-value [3]		0.272		0.062	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	8	57	101	
Mean (StdDev)	37.57 (3.512)	46.44 (6.850)	42.58 (11.034)	43.09 (10.722)	
Median	39.59	45.68	39.59	39.59	
Min, Max	33.5, 39.6	33.5, 57.8	21.3, 63.9	15.3, 63.9	
C5D1 CFB					
n	3	8	55	97	
LS Mean (StdErr) [2]	-5.45 (5.724)	8.24 (5.055)	2.06 (1.390)	4.44 (1.083)	
95% CI [2]	-18.98, 8.09	-3.71, 20.19	-0.69, 4.81	2.30, 6.58	
Difference (95% CI) in CFB [2]		13.69 (-1.87, 29.24)		2.38 (-0.59, 5.36)	
p-value [3]		0.076		0.116	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	54	102	
Mean (StdDev)	45.68 (10.536)	43.65 (10.088)	42.52 (10.147)	42.64 (10.920)	
Median	39.59	45.68	39.59	45.68	
Min, Max	39.6, 57.8	21.3, 57.8	27.4, 63.9	15.3, 63.9	
C6D1 CFB					
n	3	9	52	98	
LS Mean (StdErr) [2]	4.26 (4.721)	9.12 (4.173)	1.19 (1.420)	3.79 (1.089)	
95% CI [2]	-6.63, 15.15	-0.50, 18.75	-1.61, 4.00	1.63, 5.94	
Difference (95% CI) in CFB [2]		4.87 (-7.61, 17.34)		2.59 (-0.46, 5.64)	
p-value [3]		0.395		0.095	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Health T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	8	55	103	
Mean (StdDev)	43.65 (3.512)	45.68 (9.755)	42.25 (10.967)	43.43 (12.106)	
Median	45.68	45.68	45.68	45.68	
Min, Max	39.6, 45.7	33.5, 57.8	15.3, 63.9	15.3, 63.9	
C7D1 CFB					
n	3	8	53	99	
LS Mean (StdErr) [2]	2.20 (4.990)	12.34 (4.406)	1.49 (1.638)	4.30 (1.240)	
95% CI [2]	-9.60, 14.00	1.92, 22.75	-1.75, 4.72	1.85, 6.75	
Difference (95% CI) in CFB [2]		10.14 (-3.42, 23.70)		2.82 (-0.63, 6.26)	
Hedges'G (95% CI) in CFB		0.79 (-0.58, 2.61)		0.23 (-0.10, 0.57)	
p-value [3]		0.120		0.108	
					0.501

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	61	108	
Mean (StdDev)	44.35 (11.472)	29.95 (12.719)	33.79 (10.727)	33.46 (10.387)	
Median	43.52	25.43	33.53	33.47	
Min, Max	33.3, 56.2	17.1, 50.2	13.8, 60.4	10.5, 61.8	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	62	109	
Mean (StdDev)	44.89 (13.089)	33.63 (13.953)	36.11 (10.993)	37.33 (11.926)	
Median	37.89	27.99	35.34	38.67	
Min, Max	36.8, 60.0	15.0, 51.1	16.5, 61.2	13.0, 58.5	
C2D1 CFB					
n	3	10	59	105	
LS Mean (StdErr) [2]	0.36 (3.662)	3.32 (3.239)	0.88 (1.043)	2.40 (0.828)	
95% CI [2]	-7.92, 8.64	-4.00, 10.65	-1.18, 2.94	0.77, 4.04	
Difference (95% CI) in CFB [2]		2.96 (-6.50, 12.43)		1.52 (-0.72, 3.76)	
p-value [3]		0.497		0.181	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	10	60	100	
Mean (StdDev)	45.46 (12.888)	35.92 (14.634)	35.41 (10.051)	38.20 (11.793)	
Median	40.98	34.14	34.67	39.17	
Min, Max	35.4, 60.0	15.8, 58.0	15.1, 62.6	13.3, 61.4	
C3D1 CFB					
n	3	10	57	98	
LS Mean (StdErr) [2]	0.25 (4.322)	4.24 (3.823)	1.02 (1.034)	4.26 (0.810)	
95% CI [2]	-9.52, 10.03	-4.41, 12.89	-1.02, 3.06	2.66, 5.86	
Difference (95% CI) in CFB [2]		3.99 (-7.18, 15.16)		3.24 (1.02, 5.46)	
p-value [3]		0.440		0.005	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	2	9	54	101	
Mean (StdDev)	46.36 (14.322)	38.84 (14.698)	35.98 (10.671)	38.24 (11.388)	
Median	46.36	43.72	35.82	39.64	
Min, Max	36.2, 56.5	18.1, 59.8	10.8, 61.5	12.8, 58.5	
C4D1 CFB					
n	2	9	51	98	
LS Mean (StdErr) [2]	4.50 (6.335)	7.54 (4.229)	1.02 (1.173)	3.59 (0.932)	
95% CI [2]	-10.48, 19.48	-2.46, 17.54	-1.30, 3.34	1.75, 5.43	
Difference (95% CI) in CFB [2]		3.04 (-12.73, 18.82)		2.57 (0.11, 5.03)	
p-value [3]		0.662		0.041	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	8	57	101	
Mean (StdDev)	45.94 (8.820)	35.48 (16.463)	35.76 (11.286)	38.14 (11.913)	
Median	48.88	37.68	36.02	38.58	
Min, Max	36.0, 52.9	15.4, 57.1	13.5, 60.1	13.0, 64.3	
C5D1 CFB					
n	3	8	55	96	
LS Mean (StdErr) [2]	2.08 (4.746)	5.59 (4.191)	0.79 (1.110)	4.14 (0.872)	
95% CI [2]	-9.14, 13.31	-4.32, 15.50	-1.41, 2.98	2.41, 5.86	
Difference (95% CI) in CFB [2]		3.50 (-9.40, 16.40)		3.35 (0.98, 5.73)	
p-value [3]		0.541		0.006	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	54	102	
Mean (StdDev)	45.16 (11.538)	39.09 (14.725)	34.69 (11.035)	40.13 (11.882)	
Median	41.33	46.60	32.98	41.13	
Min, Max	36.0, 58.1	17.3, 54.8	16.4, 58.8	17.5, 61.0	
C6D1 CFB					
n	3	9	52	97	
LS Mean (StdErr) [2]	-0.30 (6.156)	5.64 (5.442)	0.10 (1.159)	5.96 (0.897)	
95% CI [2]	-14.49, 13.90	-6.91, 18.18	-2.19, 2.39	4.19, 7.73	
Difference (95% CI) in CFB [2]		5.93 (-10.33, 22.20)		5.86 (3.37, 8.35)	
p-value [3]		0.425		<0.0001	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	8	55	103	
Mean (StdDev)	44.83 (10.931)	42.33 (14.936)	36.85 (11.167)	39.19 (12.076)	
Median	41.40	45.21	36.75	38.83	
Min, Max	36.0, 57.1	17.0, 56.2	14.5, 63.2	12.5, 63.1	
C7D1 CFB					
n	3	8	53	98	
LS Mean (StdErr) [2]	0.09 (4.931)	9.06 (4.355)	0.77 (1.194)	3.93 (0.913)	
95% CI [2]	-11.57, 11.75	-1.23, 19.36	-1.59, 3.13	2.13, 5.73	
Difference (95% CI) in CFB [2]		8.98 (-4.43, 22.38)		3.16 (0.65, 5.67)	
Hedges'G (95% CI) in CFB		0.71 (-0.67, 2.49)		0.35 (0.02, 0.70)	
p-value [3]		0.157		0.014	
					0.273

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	3	10	61	108	
Mean (StdDev)	40.01 (16.122)	38.54 (10.126)	40.64 (10.355)	40.06 (10.084)	
Median	34.13	35.68	39.58	39.87	
Min, Max	27.7, 58.2	26.2, 61.0	19.2, 58.7	13.2, 61.2	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	3	10	62	109	
Mean (StdDev)	42.25 (9.971)	41.02 (11.539)	42.25 (11.024)	41.92 (10.410)	
Median	44.47	42.00	42.26	41.13	
Min, Max	31.4, 50.9	19.6, 64.8	19.9, 64.4	19.0, 63.4	
C2D1 CFB					
n	3	10	59	105	
LS Mean (StdErr) [2]	2.92 (4.173)	4.24 (3.691)	2.16 (1.167)	2.81 (0.926)	
95% CI [2]	-6.52, 12.36	-4.11, 12.59	-0.14, 4.46	0.98, 4.64	
Difference (95% CI) in CFB [2]		1.33 (-9.46, 12.12)		0.64 (-1.86, 3.15)	
p-value [3]		0.787		0.612	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	3	10	60	100	
Mean (StdDev)	38.80 (9.591)	44.19 (10.282)	43.67 (11.078)	42.82 (10.570)	
Median	35.42	45.94	43.95	44.47	
Min, Max	31.4, 49.6	21.4, 58.3	11.2, 63.3	13.8, 66.0	
C3D1 CFB					
n	3	10	57	98	
LS Mean (StdErr) [2]	0.63 (5.506)	9.78 (4.870)	3.37 (1.219)	3.55 (0.955)	
95% CI [2]	-11.82, 13.09	-1.23, 20.80	0.96, 5.78	1.67, 5.44	
Difference (95% CI) in CFB [2]		9.15 (-5.08, 23.38)		0.18 (-2.44, 2.80)	
p-value [3]		0.180		0.891	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	2	9	54	101	
Mean (StdDev)	36.14 (8.757)	44.26 (9.919)	42.26 (10.179)	43.65 (11.137)	
Median	36.14	45.70	41.13	43.71	
Min, Max	29.9, 42.3	26.1, 60.6	22.0, 59.7	13.7, 63.9	
C4D1 CFB					
n	2	9	51	98	
LS Mean (StdErr) [2]	11.11 (6.943)	10.07 (4.634)	2.08 (1.445)	3.96 (1.148)	
95% CI [2]	-5.31, 27.52	-0.88, 21.03	-0.77, 4.94	1.69, 6.23	
Difference (95% CI) in CFB [2]		-1.03 (-18.32, 16.26)		1.88 (-1.15, 4.91)	
p-value [3]		0.892		0.223	

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Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	3	8	57	101	
Mean (StdDev)	39.52 (8.907)	47.68 (7.924)	42.79 (11.928)	43.87 (10.965)	
Median	37.37	48.50	42.70	44.91	
Min, Max	31.9, 49.3	39.1, 61.7	14.1, 61.6	19.5, 64.4	
C5D1 CFB					
n	3	8	55	96	
LS Mean (StdErr) [2]	-0.06 (5.706)	8.28 (5.039)	2.42 (1.518)	4.49 (1.193)	
95% CI [2]	-13.56, 13.43	-3.63, 20.20	-0.58, 5.42	2.14, 6.85	
Difference (95% CI) in CFB [2]		8.35 (-7.16, 23.86)		2.07 (-1.18, 5.32)	
p-value [3]		0.244		0.210	

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Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-pp-thpy-a.sas Date: 15:59/07AUG2023

Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	3	9	54	102	
Mean (StdDev)	39.70 (11.427)	45.00 (9.711)	43.20 (10.775)	42.70 (11.255)	
Median	37.37	44.46	40.29	43.18	
Min, Max	29.6, 52.1	26.1, 58.5	24.1, 61.4	12.1, 61.5	
C6D1 CFB					
n	3	9	52	97	
LS Mean (StdErr) [2]	2.10 (7.778)	10.08 (6.875)	2.07 (1.477)	2.74 (1.142)	
95% CI [2]	-15.83, 20.04	-5.78, 25.93	-0.85, 4.99	0.48, 5.00	
Difference (95% CI) in CFB [2]		7.97 (-12.57, 28.52)		0.67 (-2.50, 3.84)	
p-value [3]		0.397		0.678	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 35.2.10.2.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=3)	Avapritinib 25 mg (N=10)	Placebo (N=64)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	3	8	55	103	
Mean (StdDev)	39.29 (5.633)	46.76 (7.708)	42.71 (11.747)	43.64 (11.807)	
Median	37.37	45.15	42.98	44.53	
Min, Max	34.9, 45.6	38.0, 60.6	12.1, 64.9	12.0, 63.3	
C7D1 CFB					
n	3	8	53	98	
LS Mean (StdErr) [2]	0.34 (4.955)	10.56 (4.376)	1.69 (1.510)	3.76 (1.154)	
95% CI [2]	-11.38, 12.05	0.21, 20.91	-1.30, 4.67	1.47, 6.04	
Difference (95% CI) in CFB [2]		10.22 (-3.24, 23.69)		2.07 (-1.10, 5.25)	
Hedges'G (95% CI) in CFB		0.80 (-0.56, 2.63)		0.18 (-0.15, 0.52)	
p-value [3]		0.116		0.199	
					0.305

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
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Table 04a
Time to Improvement in Weeks for SF-12
Per Protocol Population
Part 2 Baseline

SF-12 PCS Change from Baseline >= 9.1	Placebo (N=67) n/N (%)	Placebo (N=67) Median in Weeks (95% CIs) [1]	Avapritinib 25 mg (N=123) n/N (%)	Avapritinib 25 mg (N=123) Median in Weeks (95% CIs) [1]	Avapritinib 25 mg vs. Placebo HR [2] (95% CIs) P-Value	Interaction p-value [3]
Overall	23/ 67 (34.3)	27.143 (27.143, NA)	63/123 (51.2)	20.143 (16.143, NA)	1.645 (1.018, 2.656) 0.0419	
Age Group (Years)						0.503
< 65	20/ 56 (35.7)	27.143 (27.143, NA)	59/117 (50.4)	20.143 (16.143, NA)	1.557 (0.936, 2.590) 0.0884	
>= 65	3/ 11 (27.3)	NA (8.143, NA)	4/ 6 (66.7)	16.000 (8.286, NA)	2.390 (0.531, 10.748) 0.2562	
Sex						0.683
Male	4/ 15 (26.7)	27.143 (NA, NA)	16/ 35 (45.7)	NA (16.429, NA)	2.758 (0.803, 9.476) 0.1072	
Female	19/ 52 (36.5)	NA (24.143, NA)	47/ 88 (53.4)	19.857 (12.143, NA)	1.570 (0.919, 2.681) 0.0988	
Region						0.456
North America	10/ 32 (31.3)	27.143 (NA, NA)	30/ 52 (57.7)	19.286 (8.429, 27.429)	1.928 (0.938, 3.959) 0.0740	
Europe	13/ 35 (37.1)	NA (23.857, NA)	33/ 71 (46.5)	NA (16.429, NA)	1.434 (0.754, 2.726) 0.2717	

Abbreviations: NA = Not Available, HR = Hazard Ratio, CIs = Confidence Limits
Time to improvement is defined as time from first dose date to first time patient reached improvement (as defined in the table). Patients without improvement will be censored at the date of last available data.
[1] Median time to improvement is calculated based on Kaplan-Meier method.
[2] Hazard Ratio (HR) is calculated based on Cox proportional hazards model. HR > 1 correspond to a benefit for Avapritinib.
[3] Two-sided p-values for treatment-by-subgroup interaction are from Cox proportional hazards model with treatment, subgroup, treatment*subgroup in the model.
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Table 04a
Time to Improvement in Weeks for SF-12
Per Protocol Population
Part 2 Baseline

SF-12 PCS Change from Baseline >= 9.1	Placebo (N=67) n/N (%)	Placebo (N=67) Median in Weeks (95% CIs) [1]	Avapritinib 25 mg (N=123) n/N (%)	Avapritinib 25 mg (N=123) Median in Weeks (95% CIs) [1]	Avapritinib 25 mg vs. Placebo HR [2] (95% CIs) P-Value	Inter-action p-value [3]
Country						NA
BEL	1/ 1 (100.0)	4.000 (NA, NA)	1/ 2 (50.0)	NA (4.143, NA)	NA (NA, NA) NA	
CAN	2/ 5 (40.0)	NA (3.857, NA)	5/ 8 (62.5)	19.857 (4.286, 27.429)	NA (NA, NA) NA	
CHE	0/ 1 (0.0)	NA (NA, NA)	0/ 2 (0.0)	NA (NA, NA)	NA (NA, NA) NA	
DEU	6/ 14 (42.9)	NA (12.286, NA)	6/ 17 (35.3)	NA (16.429, NA)	NA (NA, NA) NA	
DNK	0/ 0	NA (NA, NA)	1/ 1 (100.0)	4.143 (NA, NA)	NA (NA, NA) NA	
ESP	0/ 3 (0.0)	NA (NA, NA)	8/ 13 (61.5)	8.429 (8.143, NA)	NA (NA, NA) NA	
FRA	3/ 5 (60.0)	16.000 (4.143, NA)	6/ 10 (60.0)	19.643 (4.143, NA)	NA (NA, NA) NA	
GBR	0/ 5 (0.0)	NA (NA, NA)	3/ 10 (30.0)	NA (20.143, NA)	NA (NA, NA) NA	
ITA	0/ 0	NA (NA, NA)	1/ 3 (33.3)	NA (4.000, NA)	NA (NA, NA) NA	
NLD	2/ 3 (66.7)	20.143 (12.143, NA)	4/ 7 (57.1)	16.143 (12.143, NA)	NA (NA, NA) NA	
NOR	1/ 2 (50.0)	NA (23.857, NA)	2/ 5 (40.0)	NA (12.286, NA)	NA (NA, NA) NA	
SWE	0/ 1 (0.0)	NA (NA, NA)	1/ 1 (100.0)	20.000 (NA, NA)	NA (NA, NA) NA	
USA	8/ 27 (29.6)	27.143 (NA, NA)	25/ 44 (56.8)	19.286 (8.429, NA)	NA (NA, NA) NA	

Abbreviations: NA = Not Available, HR = Hazard Ratio, CIs = Confidence Limits
Time to improvement is defined as time from first dose date to first time patient reached improvement (as defined in the table). Patients without improvement will be censored at the date of last available data.
[1] Median time to improvement is calculated based on Kaplan-Meier method.
[2] Hazard Ratio (HR) is calculated based on Cox proportional hazards model. HR > 1 correspond to a benefit for Avapritinib.
[3] Two-sided p-values for treatment-by-subgroup interaction are from Cox proportional hazards model with treatment, subgroup, treatment*subgroup in the model.
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Table 04a
Time to Improvement in Weeks for SF-12
Per Protocol Population
Part 2 Baseline

SF-12 PCS Change from Baseline >= 9.1	Placebo (N=67) n/N (%)	Placebo (N=67) Median in Weeks (95% CIs) [1]	Avapritinib 25 mg (N=123) n/N (%)	Avapritinib 25 mg (N=123) Median in Weeks (95% CIs) [1]	Avapritinib 25 mg vs. Placebo HR [2] (95% CIs) P-Value	Interaction p-value [3]
Baseline ISM Status						0.872
Moderate	5/ 22 (22.7)	NA (NA, NA)	15/ 37 (40.5)	NA (19.857, NA)	1.815 (0.660, 4.996) 0.2484	
Severe	18/ 45 (40.0)	27.143 (23.857, NA)	48/ 86 (55.8)	19.286 (12.143, NA)	1.610 (0.933, 2.777) 0.0869	
Baseline Serum Tryptase (ng/mL)						0.577
< 20	2/ 13 (15.4)	NA (NA, NA)	10/ 26 (38.5)	NA (19.571, NA)	2.522 (0.552, 11.518) 0.2325	
>= 20	21/ 54 (38.9)	27.143 (24.143, NA)	53/ 97 (54.6)	19.857 (12.143, NA)	1.597 (0.961, 2.654) 0.0707	
ECOG Status						0.518
0 or 1	21/ 63 (33.3)	27.143 (27.143, NA)	58/114 (50.9)	20.143 (12.429, NA)	1.737 (1.053, 2.865) 0.0306	
2+	2/ 4 (50.0)	NA (4.286, NA)	5/ 9 (55.6)	27.429 (12.143, 27.429)	0.918 (0.167, 5.037) 0.9214	
Prior TKI therapy						0.980
Yes	0/ 3 (0.0)	NA (NA, NA)	5/ 10 (50.0)	12.143 (8.286, NA)	43339354.322 (0.000, NA) 0.9969	
No	23/ 64 (35.9)	27.143 (27.143, NA)	58/113 (51.3)	20.143 (16.143, NA)	1.547 (0.953, 2.511) 0.0779	

Abbreviations: NA = Not Available, HR = Hazard Ratio, CIs = Confidence Limits
Time to improvement is defined as time from first dose date to first time patient reached improvement (as defined in the table). Patients without improvement will be censored at the date of last available data.
[1] Median time to improvement is calculated based on Kaplan-Meier method.
[2] Hazard Ratio (HR) is calculated based on Cox proportional hazards model. HR > 1 correspond to a benefit for Avapritinib.
[3] Two-sided p-values for treatment-by-subgroup interaction are from Cox proportional hazards model with treatment, subgroup, treatment*subgroup in the model.
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Table 04a
Time to Improvement in Weeks for SF-12
Per Protocol Population
Part 2 Baseline

SF-12 MCS Change from Baseline >= 8.5	Placebo (N=67) n/N (%)	Placebo (N=67) Median in Weeks (95% CIs) [1]	Avapritinib 25 mg (N=123) n/N (%)	Avapritinib 25 mg (N=123) Median in Weeks (95% CIs) [1]	Avapritinib 25 mg vs. Placebo HR [2] (95% CIs) P-Value	Interaction p-value [3]
Overall	29/ 67 (43.3)	24.429 (20.143, NA)	63/123 (51.2)	23.857 (12.143, NA)	1.217 (0.784, 1.891) 0.3810	
Age Group (Years)						0.080
< 65	26/ 56 (46.4)	24.429 (16.286, NA)	58/117 (49.6)	24.000 (12.429, NA)	1.063 (0.669, 1.689) 0.7959	
>= 65	3/ 11 (27.3)	NA (24.143, NA)	5/ 6 (83.3)	10.143 (8.143, 12.143)	4.586 (1.026, 20.506) 0.0463	
Sex						0.517
Male	6/ 15 (40.0)	NA (10.143, NA)	14/ 35 (40.0)	NA (20.286, NA)	0.935 (0.359, 2.435) 0.8902	
Female	23/ 52 (44.2)	24.429 (20.000, NA)	49/ 88 (55.7)	16.143 (12.000, NA)	1.357 (0.826, 2.230) 0.2287	
Region						0.294
North America	11/ 32 (34.4)	NA (20.857, NA)	26/ 52 (50.0)	23.857 (12.000, NA)	1.607 (0.792, 3.261) 0.1888	
Europe	18/ 35 (51.4)	24.143 (8.143, NA)	37/ 71 (52.1)	24.000 (12.143, NA)	0.993 (0.565, 1.745) 0.9815	

Abbreviations: NA = Not Available, HR = Hazard Ratio, CIs = Confidence Limits
Time to improvement is defined as time from first dose date to first time patient reached improvement (as defined in the table). Patients without improvement will be censored at the date of last available data.
[1] Median time to improvement is calculated based on Kaplan-Meier method.
[2] Hazard Ratio (HR) is calculated based on Cox proportional hazards model. HR > 1 correspond to a benefit for Avapritinib.
[3] Two-sided p-values for treatment-by-subgroup interaction are from Cox proportional hazards model with treatment, subgroup, treatment*subgroup in the model.
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Table 04a
Time to Improvement in Weeks for SF-12
Per Protocol Population
Part 2 Baseline

SF-12 MCS Change from Baseline >= 8.5	Placebo (N=67) n/N (%)	Placebo (N=67) Median in Weeks (95% CIs) [1]	Avapritinib 25 mg (N=123) n/N (%)	Avapritinib 25 mg (N=123) Median in Weeks (95% CIs) [1]	Avapritinib 25 mg vs. Placebo HR [2] (95% CIs) P-Value	Inter-action p-value [3]
Country						NA
BEL	1/ 1 (100.0)	8.000 (NA, NA)	0/ 2 (0.0)	NA (NA, NA)	NA (NA, NA) NA	
CAN	0/ 5 (0.0)	NA (NA, NA)	5/ 8 (62.5)	11.571 (8.143, NA)	NA (NA, NA) NA	
CHE	1/ 1 (100.0)	4.286 (NA, NA)	0/ 2 (0.0)	NA (NA, NA)	NA (NA, NA) NA	
DEU	9/ 14 (64.3)	8.214 (4.143, NA)	6/ 17 (35.3)	NA (16.143, NA)	NA (NA, NA) NA	
DNK	0/ 0	NA (NA, NA)	1/ 1 (100.0)	17.143 (NA, NA)	NA (NA, NA) NA	
ESP	0/ 3 (0.0)	NA (NA, NA)	4/ 13 (30.8)	NA (20.286, NA)	NA (NA, NA) NA	
FRA	3/ 5 (60.0)	24.143 (16.286, NA)	7/ 10 (70.0)	8.500 (4.143, NA)	NA (NA, NA) NA	
GBR	3/ 5 (60.0)	8.143 (4.143, NA)	5/ 10 (50.0)	NA (8.143, NA)	NA (NA, NA) NA	
ITA	0/ 0	NA (NA, NA)	3/ 3 (100.0)	8.143 (4.000, 16.286)	NA (NA, NA) NA	
NLD	1/ 3 (33.3)	NA (20.143, NA)	7/ 7 (100.0)	12.143 (4.143, 12.143)	NA (NA, NA) NA	
NOR	0/ 2 (0.0)	NA (NA, NA)	3/ 5 (60.0)	12.143 (4.143, NA)	NA (NA, NA) NA	
SWE	0/ 1 (0.0)	NA (NA, NA)	1/ 1 (100.0)	8.286 (NA, NA)	NA (NA, NA) NA	
USA	11/ 27 (40.7)	24.429 (16.286, NA)	21/ 44 (47.7)	24.000 (12.143, NA)	NA (NA, NA) NA	

Abbreviations: NA = Not Available, HR = Hazard Ratio, CIs = Confidence Limits
Time to improvement is defined as time from first dose date to first time patient reached improvement (as defined in the table). Patients without improvement will be censored at the date of last available data.
[1] Median time to improvement is calculated based on Kaplan-Meier method.
[2] Hazard Ratio (HR) is calculated based on Cox proportional hazards model. HR > 1 correspond to a benefit for Avapritinib.
[3] Two-sided p-values for treatment-by-subgroup interaction are from Cox proportional hazards model with treatment, subgroup, treatment*subgroup in the model.
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Table 04a
Time to Improvement in Weeks for SF-12
Per Protocol Population
Part 2 Baseline

SF-12 MCS Change from Baseline >= 8.5	Placebo (N=67) n/N (%)	Placebo (N=67) Median in Weeks (95% CIs) [1]	Avapritinib 25 mg (N=123) n/N (%)	Avapritinib 25 mg (N=123) Median in Weeks (95% CIs) [1]	Avapritinib 25 mg vs. Placebo HR [2] (95% CIs) P-Value	Interaction p-value [3]
Baseline ISM Status						0.067
Moderate	4/ 22 (18.2)	NA (NA, NA)	17/ 37 (45.9)	NA (8.286, NA)	2.740 (0.921, 8.148) 0.0699	
Severe	25/ 45 (55.6)	20.143 (10.143, NA)	46/ 86 (53.5)	17.143 (12.143, NA)	0.943 (0.579, 1.535) 0.8122	
Baseline Serum Tryptase (ng/mL)						0.768
< 20	7/ 13 (53.8)	24.429 (4.143, NA)	15/ 26 (57.7)	16.214 (7.714, NA)	1.078 (0.439, 2.649) 0.8694	
>= 20	22/ 54 (40.7)	NA (20.143, NA)	48/ 97 (49.5)	24.000 (12.143, NA)	1.244 (0.751, 2.061) 0.3971	
ECOG Status						0.282
0 or 1	26/ 63 (41.3)	24.429 (20.286, NA)	58/114 (50.9)	24.000 (12.286, NA)	1.291 (0.813, 2.051) 0.2796	
2+	3/ 4 (75.0)	6.214 (4.143, NA)	5/ 9 (55.6)	10.857 (8.143, NA)	0.558 (0.132, 2.363) 0.4282	
Prior TKI therapy						0.521
Yes	1/ 3 (33.3)	NA (4.286, NA)	6/ 10 (60.0)	8.714 (8.143, NA)	1.976 (0.236, 16.551) 0.5298	
No	28/ 64 (43.8)	24.429 (20.143, NA)	57/113 (50.4)	24.000 (12.429, NA)	1.168 (0.743, 1.837) 0.5013	

Abbreviations: NA = Not Available, HR = Hazard Ratio, CIs = Confidence Limits
Time to improvement is defined as time from first dose date to first time patient reached improvement (as defined in the table). Patients without improvement will be censored at the date of last available data.
[1] Median time to improvement is calculated based on Kaplan-Meier method.
[2] Hazard Ratio (HR) is calculated based on Cox proportional hazards model. HR > 1 correspond to a benefit for Avapritinib.
[3] Two-sided p-values for treatment-by-subgroup interaction are from Cox proportional hazards model with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.1a
Summary of All Adverse Events by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Overall	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	P-Value [3]
Any AEs, n (%)	51 (91.1)	108 (92.3)	11 (100.0)	6 (100.0)	>0.999
Odds Ratio (95% CIs) [1], P-Value		1.176 (0.375, 3.689), 0.780		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		1.014 (0.920, 1.117), 0.786		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.012 (-0.077, 0.101), 0.785		NA (NA, NA), NA	
AEs Related to Study Drug, n (%)	27 (48.2)	63 (53.8)	4 (36.4)	6 (100.0)	0.945
Odds Ratio (95% CIs) [1], P-Value		1.253 (0.662, 2.371), 0.488		NE (NE, NE), 0.011	
Relative Risk (95% CIs) [2], P-Value		1.117 (0.812, 1.537), 0.497		2.750 (1.258, 6.010), 0.011	
Risk Difference (95% CIs) [2], P-Value		0.056 (-0.103, 0.215), 0.488		0.636 (0.352, 0.921), <0.0001	
Serious AEs, n (%)	6 (10.7)	6 (5.1)	2 (18.2)	0	0.964
Odds Ratio (95% CIs) [1], P-Value		0.450 (0.138, 1.466), 0.176		NE (NE, NE), 0.266	
Relative Risk (95% CIs) [2], P-Value		0.479 (0.162, 1.418), 0.184		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.056 (-0.146, 0.034), 0.225		-0.182 (-0.410, 0.046), 0.118	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.1a
Summary of All Adverse Events by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Overall	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	P-Value [3]
Grade 1-2 AEs, n (%)	50 (89.3)	108 (92.3)	11 (100.0)	6 (100.0)	0.998
Odds Ratio (95% CIs) [1], P-Value		1.440 (0.486, 4.266), 0.509		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		1.034 (0.931, 1.148), 0.533		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.030 (-0.064, 0.125), 0.530		NA (NA, NA), NA	
Grade 1-2 AEs Related to Study Drug, n (%)	27 (48.2)	63 (53.8)	4 (36.4)	6 (100.0)	0.945
Odds Ratio (95% CIs) [1], P-Value		1.253 (0.662, 2.371), 0.488		NE (NE, NE), 0.011	
Relative Risk (95% CIs) [2], P-Value		1.117 (0.812, 1.537), 0.497		2.750 (1.258, 6.010), 0.011	
Risk Difference (95% CIs) [2], P-Value		0.056 (-0.103, 0.215), 0.488		0.636 (0.352, 0.921), <0.0001	
Grade >=3 AEs, n (%)	12 (21.4)	26 (22.2)	2 (18.2)	0	0.962
Odds Ratio (95% CIs) [1], P-Value		1.048 (0.484, 2.269), 0.906		NE (NE, NE), 0.266	
Relative Risk (95% CIs) [2], P-Value		1.037 (0.566, 1.900), 0.906		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.008 (-0.123, 0.139), 0.906		-0.182 (-0.410, 0.046), 0.118	
Grade >=3 AEs Related to Study Drug, n (%)	2 (3.6)	1 (0.9)	0	0	0.995
Odds Ratio (95% CIs) [1], P-Value		0.233 (0.021, 2.623), 0.200		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		0.239 (0.022, 2.584), 0.239		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.027 (-0.079, 0.024), 0.300		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.1a
Summary of All Adverse Events by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Overall	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	7 (12.5)	11 (9.4)	2 (18.2)	0	0.957
Odds Ratio (95% CIs) [1], P-Value		0.726 (0.266, 1.987), 0.532		NE (NE, NE), 0.266	
Relative Risk (95% CIs) [2], P-Value		0.752 (0.308, 1.836), 0.532		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.031 (-0.132, 0.071), 0.550		-0.182 (-0.410, 0.046), 0.118	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	1 (1.8)	2 (1.7)	0	0	>0.999
Odds Ratio (95% CIs) [1], P-Value		0.957 (0.085, 10.777), 0.971		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		0.957 (0.089, 10.335), 0.971		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.001 (-0.043, 0.041), 0.972		NA (NA, NA), NA	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	1 (1.8)	1 (0.9)	0	0	0.998
Odds Ratio (95% CIs) [1], P-Value		0.474 (0.029, 7.722), 0.592		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		0.479 (0.030, 7.513), 0.600		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.009 (-0.048, 0.029), 0.635		NA (NA, NA), NA	
Related AEs Leading to Interruption of Study Drug, n (%)	3 (5.4)	5 (4.3)	1 (9.1)	0	0.956
Odds Ratio (95% CIs) [1], P-Value		0.789 (0.182, 3.424), 0.751		NE (NE, NE), 0.446	
Relative Risk (95% CIs) [2], P-Value		0.798 (0.198, 3.220), 0.751		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.011 (-0.080, 0.059), 0.760		-0.091 (-0.261, 0.079), 0.294	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.1a
Summary of All Adverse Events by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Overall	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	1 (1.8)	1 (0.9)	0	0	0.998
Odds Ratio (95% CIs) [1], P-Value		0.474 (0.029, 7.722), 0.592		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		0.479 (0.030, 7.513), 0.600		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.009 (-0.048, 0.029), 0.635		NA (NA, NA), NA	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	1 (1.8)	1 (0.9)	0	0	0.998
Odds Ratio (95% CIs) [1], P-Value		0.474 (0.029, 7.722), 0.592		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		0.479 (0.030, 7.513), 0.600		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.009 (-0.048, 0.029), 0.635		NA (NA, NA), NA	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.1a
Summary of All Adverse Events by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Cognitive Effects AESI	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	P-Value [3]
Any AEs, n (%)	2 (3.6)	4 (3.4)	1 (9.1)	0	0.959
Odds Ratio (95% CIs) [1], P-Value		0.956 (0.170, 5.381), 0.959		NE (NE, NE), 0.446	
Relative Risk (95% CIs) [2], P-Value		0.957 (0.181, 5.071), 0.959		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.002 (-0.060, 0.057), 0.959		-0.091 (-0.261, 0.079), 0.294	
AEs Related to Study Drug, n (%)	2 (3.6)	3 (2.6)	0	0	0.998
Odds Ratio (95% CIs) [1], P-Value		0.711 (0.115, 4.378), 0.711		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		0.718 (0.123, 4.176), 0.712		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.010 (-0.066, 0.046), 0.726		NA (NA, NA), NA	
Serious AEs, n (%)	0	0	1 (9.1)	0	0.967
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.446	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.091 (-0.261, 0.079), 0.294	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.1a
Summary of All Adverse Events by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Cognitive Effects AESI	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	P-Value [3]
Grade 1-2 AEs, n (%)	2 (3.6)	4 (3.4)	0	0	>0.999
Odds Ratio (95% CIs) [1], P-Value		0.956 (0.170, 5.381), 0.959		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		0.957 (0.181, 5.071), 0.959		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.002 (-0.060, 0.057), 0.959		NA (NA, NA), NA	
Grade 1-2 AEs Related to Study Drug, n (%)	2 (3.6)	3 (2.6)	0	0	0.998
Odds Ratio (95% CIs) [1], P-Value		0.711 (0.115, 4.378), 0.711		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		0.718 (0.123, 4.176), 0.712		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.010 (-0.066, 0.046), 0.726		NA (NA, NA), NA	
Grade >=3 AEs, n (%)	0	0	1 (9.1)	0	0.967
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.446	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.091 (-0.261, 0.079), 0.294	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.1a
Summary of All Adverse Events by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Cognitive Effects AESI	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	0	2 (1.7)	0	0	0.976
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.325		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.017 (-0.006, 0.041), 0.154		NA (NA, NA), NA	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	1 (1.8)	1 (0.9)	0	0	0.998
Odds Ratio (95% CIs) [1], P-Value		0.474 (0.029, 7.722), 0.592		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		0.479 (0.030, 7.513), 0.600		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.009 (-0.048, 0.029), 0.635		NA (NA, NA), NA	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Interruption of Study Drug, n (%)	0	2 (1.7)	0	0	0.976
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.325		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.017 (-0.006, 0.041), 0.154		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.1a
Summary of All Adverse Events by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Cognitive Effects AESI	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	1 (1.8)	1 (0.9)	0	0	0.998
Odds Ratio (95% CIs) [1], P-Value		0.474 (0.029, 7.722), 0.592		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		0.479 (0.030, 7.513), 0.600		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.009 (-0.048, 0.029), 0.635		NA (NA, NA), NA	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.1a
Summary of All Adverse Events by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Intracranial Bleeding AESI	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	P-Value [3]
Any AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Serious AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.1a
Summary of All Adverse Events by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Intracranial Bleeding AESI	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	P-Value [3]
Grade 1-2 AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade 1-2 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade >=3 AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.1a
Summary of All Adverse Events by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Intracranial Bleeding AESI	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Interruption of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.1a
Summary of All Adverse Events by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Intracranial Bleeding AESI	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.1a
Summary of All Adverse Events by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Oedema CMQ	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	P-Value [3]
Any AEs, n (%)	8 (14.3)	29 (24.8)	0	5 (83.3)	0.936
Odds Ratio (95% CIs) [1], P-Value		1.977 (0.838, 4.664), 0.115		NE (NE, NE), <0.001	
Relative Risk (95% CIs) [2], P-Value		1.735 (0.849, 3.547), 0.131		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.105 (-0.015, 0.226), 0.088		0.833 (0.535, 1.000), <0.0001	
AEs Related to Study Drug, n (%)	5 (8.9)	19 (16.2)	0	5 (83.3)	0.947
Odds Ratio (95% CIs) [1], P-Value		1.978 (0.698, 5.604), 0.193		NE (NE, NE), <0.001	
Relative Risk (95% CIs) [2], P-Value		1.819 (0.716, 4.620), 0.209		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.073 (-0.027, 0.173), 0.153		0.833 (0.535, 1.000), <0.0001	
Serious AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.1a
Summary of All Adverse Events by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Oedema CMQ	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	P-Value [3]
Grade 1-2 AEs, n (%)	8 (14.3)	29 (24.8)	0	5 (83.3)	0.936
Odds Ratio (95% CIs) [1], P-Value		1.977 (0.838, 4.664), 0.115		NE (NE, NE), <0.001	
Relative Risk (95% CIs) [2], P-Value		1.735 (0.849, 3.547), 0.131		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.105 (-0.015, 0.226), 0.088		0.833 (0.535, 1.000), <0.0001	
Grade 1-2 AEs Related to Study Drug, n (%)	5 (8.9)	19 (16.2)	0	5 (83.3)	0.947
Odds Ratio (95% CIs) [1], P-Value		1.978 (0.698, 5.604), 0.193		NE (NE, NE), <0.001	
Relative Risk (95% CIs) [2], P-Value		1.819 (0.716, 4.620), 0.209		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.073 (-0.027, 0.173), 0.153		0.833 (0.535, 1.000), <0.0001	
Grade >=3 AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.1a
Summary of All Adverse Events by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Oedema CMQ	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	0	1 (0.9)	0	0	0.983
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.488		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.009 (-0.008, 0.025), 0.315		NA (NA, NA), NA	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	0	1 (0.9)	0	0	0.983
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.488		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.009 (-0.008, 0.025), 0.315		NA (NA, NA), NA	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Interruption of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.1a
Summary of All Adverse Events by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Oedema CMQ	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.2a
Summary of All Adverse Events by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

	Male		Female		
Overall	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	P-Value [3]
Any AEs, n (%)	14 (93.3)	31 (88.6)	48 (92.3)	83 (94.3)	0.499
Odds Ratio (95% CIs) [1], P-Value		0.554 (0.057, 5.414), 0.607		1.383 (0.354, 5.400), 0.639	
Relative Risk (95% CIs) [2], P-Value		0.949 (0.793, 1.136), 0.569		1.022 (0.930, 1.122), 0.652	
Risk Difference (95% CIs) [2], P-Value		-0.048 (-0.212, 0.117), 0.570		0.020 (-0.067, 0.107), 0.651	
AEs Related to Study Drug, n (%)	4 (26.7)	16 (45.7)	27 (51.9)	53 (60.2)	0.510
Odds Ratio (95% CIs) [1], P-Value		2.316 (0.616, 8.700), 0.208		1.402 (0.702, 2.800), 0.337	
Relative Risk (95% CIs) [2], P-Value		1.714 (0.688, 4.274), 0.248		1.160 (0.849, 1.584), 0.351	
Risk Difference (95% CIs) [2], P-Value		0.190 (-0.088, 0.469), 0.179		0.083 (-0.087, 0.253), 0.338	
Serious AEs, n (%)	1 (6.7)	0	7 (13.5)	6 (6.8)	0.948
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.123		0.470 (0.149, 1.485), 0.191	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.506 (0.180, 1.426), 0.198	
Risk Difference (95% CIs) [2], P-Value		-0.067 (-0.193, 0.060), 0.301		-0.066 (-0.173, 0.040), 0.222	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.2a
Summary of All Adverse Events by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

	Male		Female		
Overall	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	P-Value [3]
Grade 1-2 AEs, n (%)	13 (86.7)	31 (88.6)	48 (92.3)	83 (94.3)	0.898
Odds Ratio (95% CIs) [1], P-Value		1.192 (0.194, 7.335), 0.849		1.383 (0.354, 5.400), 0.639	
Relative Risk (95% CIs) [2], P-Value		1.022 (0.811, 1.288), 0.854		1.022 (0.930, 1.122), 0.652	
Risk Difference (95% CIs) [2], P-Value		0.019 (-0.183, 0.221), 0.853		0.020 (-0.067, 0.107), 0.651	
Grade 1-2 AEs Related to Study Drug, n (%)	4 (26.7)	16 (45.7)	27 (51.9)	53 (60.2)	0.510
Odds Ratio (95% CIs) [1], P-Value		2.316 (0.616, 8.700), 0.208		1.402 (0.702, 2.800), 0.337	
Relative Risk (95% CIs) [2], P-Value		1.714 (0.688, 4.274), 0.248		1.160 (0.849, 1.584), 0.351	
Risk Difference (95% CIs) [2], P-Value		0.190 (-0.088, 0.469), 0.179		0.083 (-0.087, 0.253), 0.338	
Grade >=3 AEs, n (%)	2 (13.3)	5 (14.3)	12 (23.1)	21 (23.9)	0.971
Odds Ratio (95% CIs) [1], P-Value		1.083 (0.186, 6.324), 0.929		1.045 (0.465, 2.349), 0.916	
Relative Risk (95% CIs) [2], P-Value		1.071 (0.233, 4.919), 0.929		1.034 (0.556, 1.924), 0.916	
Risk Difference (95% CIs) [2], P-Value		0.010 (-0.198, 0.217), 0.928		0.008 (-0.137, 0.153), 0.915	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	2 (3.8)	1 (1.1)	0.996
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.287 (0.025, 3.249), 0.285	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.295 (0.027, 3.179), 0.315	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.027 (-0.084, 0.030), 0.349	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.2a
Summary of All Adverse Events by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

	Male		Female		
Overall	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	2 (13.3)	0	7 (13.5)	11 (12.5)	0.955
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.027		0.918 (0.332, 2.538), 0.870	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.929 (0.384, 2.246), 0.869	
Risk Difference (95% CIs) [2], P-Value		-0.133 (-0.305, 0.039), 0.129		-0.010 (-0.125, 0.106), 0.871	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	1 (6.7)	0	0	2 (2.3)	0.894
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.123		NE (NE, NE), 0.274	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.067 (-0.193, 0.060), 0.301		0.023 (-0.008, 0.054), 0.153	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	1 (1.9)	1 (1.1)	0.997
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.586 (0.036, 9.575), 0.705	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.591 (0.038, 9.248), 0.708	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.008 (-0.051, 0.036), 0.722	
Related AEs Leading to Interruption of Study Drug, n (%)	1 (6.7)	0	3 (5.8)	5 (5.7)	0.953
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.123		0.984 (0.225, 4.298), 0.983	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.985 (0.245, 3.953), 0.983	
Risk Difference (95% CIs) [2], P-Value		-0.067 (-0.193, 0.060), 0.301		-0.001 (-0.081, 0.079), 0.983	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.2a
Summary of All Adverse Events by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

	Male		Female		
Overall	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	1 (6.7)	0	0	1 (1.1)	0.901
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.123		NE (NE, NE), 0.440	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.067 (-0.193, 0.060), 0.301		0.011 (-0.011, 0.034), 0.315	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	1 (1.9)	1 (1.1)	0.997
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.586 (0.036, 9.575), 0.705	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.591 (0.038, 9.248), 0.708	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.008 (-0.051, 0.036), 0.722	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.2a
Summary of All Adverse Events by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

	Male		Female		
Cognitive Effects AESI	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	P-Value [3]
Any AEs, n (%)	1 (6.7)	1 (2.9)	2 (3.8)	3 (3.4)	0.658
Odds Ratio (95% CIs) [1], P-Value		0.412 (0.024, 7.053), 0.529		0.882 (0.143, 5.462), 0.893	
Relative Risk (95% CIs) [2], P-Value		0.429 (0.029, 6.409), 0.539		0.886 (0.153, 5.132), 0.893	
Risk Difference (95% CIs) [2], P-Value		-0.038 (-0.176, 0.100), 0.588		-0.004 (-0.069, 0.060), 0.894	
AEs Related to Study Drug, n (%)	1 (6.7)	0	1 (1.9)	3 (3.4)	0.941
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.123		1.800 (0.182, 17.769), 0.610	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.773 (0.189, 16.603), 0.616	
Risk Difference (95% CIs) [2], P-Value		-0.067 (-0.193, 0.060), 0.301		0.015 (-0.038, 0.068), 0.584	
Serious AEs, n (%)	0	0	1 (1.9)	0	0.967
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.192	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.019 (-0.057, 0.018), 0.313	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.2a
Summary of All Adverse Events by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

	Male		Female		
Cognitive Effects AESI	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	P-Value [3]
Grade 1-2 AEs, n (%)	1 (6.7)	1 (2.9)	1 (1.9)	3 (3.4)	0.428
Odds Ratio (95% CIs) [1], P-Value		0.412 (0.024, 7.053), 0.529		1.800 (0.182, 17.769), 0.610	
Relative Risk (95% CIs) [2], P-Value		0.429 (0.029, 6.409), 0.539		1.773 (0.189, 16.603), 0.616	
Risk Difference (95% CIs) [2], P-Value		-0.038 (-0.176, 0.100), 0.588		0.015 (-0.038, 0.068), 0.584	
Grade 1-2 AEs Related to Study Drug, n (%)	1 (6.7)	0	1 (1.9)	3 (3.4)	0.941
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.123		1.800 (0.182, 17.769), 0.610	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.773 (0.189, 16.603), 0.616	
Risk Difference (95% CIs) [2], P-Value		-0.067 (-0.193, 0.060), 0.301		0.015 (-0.038, 0.068), 0.584	
Grade >=3 AEs, n (%)	0	0	1 (1.9)	0	0.967
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.192	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.019 (-0.057, 0.018), 0.313	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.2a
Summary of All Adverse Events by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

	Male		Female		
Cognitive Effects AESI	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	0	0	0	2 (2.3)	0.961
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.274	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.023 (-0.008, 0.054), 0.153	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	1 (6.7)	0	0	1 (1.1)	0.901
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.123		NE (NE, NE), 0.440	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.067 (-0.193, 0.060), 0.301		0.011 (-0.011, 0.034), 0.315	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Interruption of Study Drug, n (%)	0	0	0	2 (2.3)	0.961
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.274	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.023 (-0.008, 0.054), 0.153	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.2a
Summary of All Adverse Events by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

	Male		Female		
Cognitive Effects AESI	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	1 (6.7)	0	0	1 (1.1)	0.901
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.123		NE (NE, NE), 0.440	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.067 (-0.193, 0.060), 0.301		0.011 (-0.011, 0.034), 0.315	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.2a
Summary of All Adverse Events by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

	Male		Female		
Intracranial Bleeding AESI	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	P-Value [3]
Any AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Serious AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.2a
Summary of All Adverse Events by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

	Male		Female		
Intracranial Bleeding AESI	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	P-Value [3]
Grade 1-2 AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade 1-2 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade >=3 AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.2a
Summary of All Adverse Events by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

	Male		Female		
Intracranial Bleeding AESI	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Interruption of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.2a
Summary of All Adverse Events by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

	Male		Female		
Intracranial Bleeding AESI	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.2a
Summary of All Adverse Events by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

	Male		Female		
Oedema CMQ	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	P-Value [3]
Any AEs, n (%)	1 (6.7)	7 (20.0)	7 (13.5)	27 (30.7)	0.864
Odds Ratio (95% CIs) [1], P-Value		3.500 (0.391, 31.314), 0.239		2.845 (1.138, 7.113), 0.022	
Relative Risk (95% CIs) [2], P-Value		3.000 (0.404, 22.303), 0.283		2.279 (1.069, 4.861), 0.033	
Risk Difference (95% CIs) [2], P-Value		0.133 (-0.050, 0.316), 0.153		0.172 (0.038, 0.306), 0.012	
AEs Related to Study Drug, n (%)	0	6 (17.1)	5 (9.6)	18 (20.5)	0.951
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.087		2.417 (0.840, 6.959), 0.094	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		2.127 (0.840, 5.390), 0.112	
Risk Difference (95% CIs) [2], P-Value		0.171 (0.047, 0.296), 0.007		0.108 (-0.008, 0.225), 0.068	
Serious AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.2a
Summary of All Adverse Events by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

	Male		Female		
Oedema CMQ	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	P-Value [3]
Grade 1-2 AEs, n (%)	1 (6.7)	7 (20.0)	7 (13.5)	27 (30.7)	0.864
Odds Ratio (95% CIs) [1], P-Value		3.500 (0.391, 31.314), 0.239		2.845 (1.138, 7.113), 0.022	
Relative Risk (95% CIs) [2], P-Value		3.000 (0.404, 22.303), 0.283		2.279 (1.069, 4.861), 0.033	
Risk Difference (95% CIs) [2], P-Value		0.133 (-0.050, 0.316), 0.153		0.172 (0.038, 0.306), 0.012	
Grade 1-2 AEs Related to Study Drug, n (%)	0	6 (17.1)	5 (9.6)	18 (20.5)	0.951
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.087		2.417 (0.840, 6.959), 0.094	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		2.127 (0.840, 5.390), 0.112	
Risk Difference (95% CIs) [2], P-Value		0.171 (0.047, 0.296), 0.007		0.108 (-0.008, 0.225), 0.068	
Grade >=3 AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.2a
Summary of All Adverse Events by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

	Male		Female		
Oedema CMQ	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	0	0	0	1 (1.1)	0.973
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.440	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.011 (-0.011, 0.034), 0.315	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	0	0	0	1 (1.1)	0.973
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.440	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.011 (-0.011, 0.034), 0.315	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Interruption of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.2a
Summary of All Adverse Events by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

	Male		Female		
Oedema CMQ	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.3a
Summary of All Adverse Events by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Overall	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	P-Value [3]
Any AEs, n (%)	28 (87.5)	47 (90.4)	34 (97.1)	67 (94.4)	0.455
Odds Ratio (95% CIs) [1], P-Value		1.343 (0.333, 5.421), 0.678		0.493 (0.053, 4.581), 0.526	
Relative Risk (95% CIs) [2], P-Value		1.033 (0.882, 1.210), 0.688		0.971 (0.896, 1.053), 0.479	
Risk Difference (95% CIs) [2], P-Value		0.029 (-0.111, 0.169), 0.686		-0.028 (-0.105, 0.049), 0.479	
AEs Related to Study Drug, n (%)	14 (43.8)	26 (50.0)	17 (48.6)	43 (60.6)	0.702
Odds Ratio (95% CIs) [1], P-Value		1.286 (0.531, 3.115), 0.578		1.626 (0.719, 3.677), 0.241	
Relative Risk (95% CIs) [2], P-Value		1.143 (0.709, 1.843), 0.584		1.247 (0.845, 1.840), 0.266	
Risk Difference (95% CIs) [2], P-Value		0.063 (-0.157, 0.282), 0.576		0.120 (-0.081, 0.321), 0.242	
Serious AEs, n (%)	4 (12.5)	2 (3.8)	4 (11.4)	4 (5.6)	0.666
Odds Ratio (95% CIs) [1], P-Value		0.280 (0.048, 1.626), 0.135		0.463 (0.109, 1.972), 0.288	
Relative Risk (95% CIs) [2], P-Value		0.308 (0.060, 1.585), 0.159		0.493 (0.131, 1.855), 0.296	
Risk Difference (95% CIs) [2], P-Value		-0.087 (-0.212, 0.039), 0.178		-0.058 (-0.176, 0.060), 0.337	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.3a
Summary of All Adverse Events by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Overall	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	P-Value [3]
Grade 1-2 AEs, n (%)	27 (84.4)	47 (90.4)	34 (97.1)	67 (94.4)	0.340
Odds Ratio (95% CIs) [1], P-Value		1.741 (0.462, 6.561), 0.409		0.493 (0.053, 4.581), 0.526	
Relative Risk (95% CIs) [2], P-Value		1.071 (0.901, 1.274), 0.437		0.971 (0.896, 1.053), 0.479	
Risk Difference (95% CIs) [2], P-Value		0.060 (-0.089, 0.209), 0.430		-0.028 (-0.105, 0.049), 0.479	
Grade 1-2 AEs Related to Study Drug, n (%)	14 (43.8)	26 (50.0)	17 (48.6)	43 (60.6)	0.702
Odds Ratio (95% CIs) [1], P-Value		1.286 (0.531, 3.115), 0.578		1.626 (0.719, 3.677), 0.241	
Relative Risk (95% CIs) [2], P-Value		1.143 (0.709, 1.843), 0.584		1.247 (0.845, 1.840), 0.266	
Risk Difference (95% CIs) [2], P-Value		0.063 (-0.157, 0.282), 0.576		0.120 (-0.081, 0.321), 0.242	
Grade >=3 AEs, n (%)	7 (21.9)	11 (21.2)	7 (20.0)	15 (21.1)	0.881
Odds Ratio (95% CIs) [1], P-Value		0.958 (0.329, 2.794), 0.938		1.071 (0.392, 2.928), 0.893	
Relative Risk (95% CIs) [2], P-Value		0.967 (0.418, 2.238), 0.938		1.056 (0.474, 2.352), 0.893	
Risk Difference (95% CIs) [2], P-Value		-0.007 (-0.188, 0.174), 0.938		0.011 (-0.152, 0.174), 0.892	
Grade >=3 AEs Related to Study Drug, n (%)	1 (3.1)	1 (1.9)	1 (2.9)	0	0.962
Odds Ratio (95% CIs) [1], P-Value		0.608 (0.037, 10.071), 0.726		NE (NE, NE), 0.152	
Relative Risk (95% CIs) [2], P-Value		0.615 (0.040, 9.498), 0.728		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.012 (-0.083, 0.059), 0.740		-0.029 (-0.084, 0.027), 0.310	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.3a
Summary of All Adverse Events by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Overall	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	5 (15.6)	5 (9.6)	4 (11.4)	6 (8.5)	0.819
Odds Ratio (95% CIs) [1], P-Value		0.574 (0.152, 2.165), 0.409		0.715 (0.188, 2.720), 0.622	
Relative Risk (95% CIs) [2], P-Value		0.615 (0.193, 1.961), 0.412		0.739 (0.223, 2.452), 0.622	
Risk Difference (95% CIs) [2], P-Value		-0.060 (-0.209, 0.089), 0.430		-0.030 (-0.153, 0.094), 0.637	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	1 (3.1)	2 (3.8)	0	0	0.999
Odds Ratio (95% CIs) [1], P-Value		1.240 (0.108, 14.254), 0.863		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		1.231 (0.116, 13.031), 0.863		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.007 (-0.073, 0.087), 0.859		NA (NA, NA), NA	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	1 (2.9)	1 (1.4)	0.997
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.486 (0.029, 8.003), 0.606	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.493 (0.032, 7.650), 0.613	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.014 (-0.076, 0.047), 0.645	
Related AEs Leading to Interruption of Study Drug, n (%)	2 (6.3)	3 (5.8)	2 (5.7)	2 (2.8)	0.639
Odds Ratio (95% CIs) [1], P-Value		0.918 (0.145, 5.817), 0.928		0.478 (0.065, 3.546), 0.462	
Relative Risk (95% CIs) [2], P-Value		0.923 (0.163, 5.228), 0.928		0.493 (0.072, 3.355), 0.470	
Risk Difference (95% CIs) [2], P-Value		-0.005 (-0.110, 0.100), 0.929		-0.029 (-0.115, 0.057), 0.509	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.3a
Summary of All Adverse Events by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Overall	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	1 (3.1)	1 (1.9)	0	0	0.998
Odds Ratio (95% CIs) [1], P-Value		0.608 (0.037, 10.071), 0.726		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		0.615 (0.040, 9.498), 0.728		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.012 (-0.083, 0.059), 0.740		NA (NA, NA), NA	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	1 (2.9)	1 (1.4)	0.997
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.486 (0.029, 8.003), 0.606	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.493 (0.032, 7.650), 0.613	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.014 (-0.076, 0.047), 0.645	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.3a
Summary of All Adverse Events by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Cognitive Effects AESI	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	P-Value [3]
Any AEs, n (%)	2 (6.3)	2 (3.8)	1 (2.9)	2 (2.8)	0.758
Odds Ratio (95% CIs) [1], P-Value		0.600 (0.080, 4.485), 0.615		0.986 (0.086, 11.254), 0.991	
Relative Risk (95% CIs) [2], P-Value		0.615 (0.091, 4.155), 0.618		0.986 (0.093, 10.505), 0.991	
Risk Difference (95% CIs) [2], P-Value		-0.024 (-0.123, 0.075), 0.634		-0.000 (-0.068, 0.067), 0.991	
AEs Related to Study Drug, n (%)	1 (3.1)	1 (1.9)	1 (2.9)	2 (2.8)	0.799
Odds Ratio (95% CIs) [1], P-Value		0.608 (0.037, 10.071), 0.726		0.986 (0.086, 11.254), 0.991	
Relative Risk (95% CIs) [2], P-Value		0.615 (0.040, 9.498), 0.728		0.986 (0.093, 10.505), 0.991	
Risk Difference (95% CIs) [2], P-Value		-0.012 (-0.083, 0.059), 0.740		-0.000 (-0.068, 0.067), 0.991	
Serious AEs, n (%)	1 (3.1)	0	0	0	0.970
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.200		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.031 (-0.092, 0.029), 0.310		NA (NA, NA), NA	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.3a
Summary of All Adverse Events by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Cognitive Effects AESI	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	P-Value [3]
Grade 1-2 AEs, n (%)	1 (3.1)	2 (3.8)	1 (2.9)	2 (2.8)	0.896
Odds Ratio (95% CIs) [1], P-Value		1.240 (0.108, 14.254), 0.863		0.986 (0.086, 11.254), 0.991	
Relative Risk (95% CIs) [2], P-Value		1.231 (0.116, 13.031), 0.863		0.986 (0.093, 10.505), 0.991	
Risk Difference (95% CIs) [2], P-Value		0.007 (-0.073, 0.087), 0.859		-0.000 (-0.068, 0.067), 0.991	
Grade 1-2 AEs Related to Study Drug, n (%)	1 (3.1)	1 (1.9)	1 (2.9)	2 (2.8)	0.799
Odds Ratio (95% CIs) [1], P-Value		0.608 (0.037, 10.071), 0.726		0.986 (0.086, 11.254), 0.991	
Relative Risk (95% CIs) [2], P-Value		0.615 (0.040, 9.498), 0.728		0.986 (0.093, 10.505), 0.991	
Risk Difference (95% CIs) [2], P-Value		-0.012 (-0.083, 0.059), 0.740		-0.000 (-0.068, 0.067), 0.991	
Grade >=3 AEs, n (%)	1 (3.1)	0	0	0	0.970
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.200		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.031 (-0.092, 0.029), 0.310		NA (NA, NA), NA	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.3a
Summary of All Adverse Events by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Cognitive Effects AESI	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	0	1 (1.9)	0	1 (1.4)	0.999
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.430		NE (NE, NE), 0.481	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.019 (-0.018, 0.057), 0.313		0.014 (-0.013, 0.041), 0.314	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	1 (3.1)	1 (1.9)	0	0	0.998
Odds Ratio (95% CIs) [1], P-Value		0.608 (0.037, 10.071), 0.726		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		0.615 (0.040, 9.498), 0.728		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.012 (-0.083, 0.059), 0.740		NA (NA, NA), NA	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Interruption of Study Drug, n (%)	0	1 (1.9)	0	1 (1.4)	0.999
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.430		NE (NE, NE), 0.481	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.019 (-0.018, 0.057), 0.313		0.014 (-0.013, 0.041), 0.314	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.3a
Summary of All Adverse Events by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Cognitive Effects AESI	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	1 (3.1)	1 (1.9)	0	0	0.998
Odds Ratio (95% CIs) [1], P-Value		0.608 (0.037, 10.071), 0.726		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		0.615 (0.040, 9.498), 0.728		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.012 (-0.083, 0.059), 0.740		NA (NA, NA), NA	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.3a
Summary of All Adverse Events by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Intracranial Bleeding AESI	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	P-Value [3]
Any AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Serious AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.3a
Summary of All Adverse Events by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Intracranial Bleeding AESI	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	P-Value [3]
Grade 1-2 AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade 1-2 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade >=3 AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.3a
Summary of All Adverse Events by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Intracranial Bleeding AESI	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Interruption of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.3a
Summary of All Adverse Events by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Intracranial Bleeding AESI	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.3a
Summary of All Adverse Events by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Oedema CMQ	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	P-Value [3]
Any AEs, n (%)	5 (15.6)	13 (25.0)	3 (8.6)	21 (29.6)	0.300
Odds Ratio (95% CIs) [1], P-Value		1.800 (0.574, 5.640), 0.309		4.480 (1.235, 16.251), 0.015	
Relative Risk (95% CIs) [2], P-Value		1.600 (0.630, 4.066), 0.323		3.451 (1.104, 10.789), 0.033	
Risk Difference (95% CIs) [2], P-Value		0.094 (-0.079, 0.266), 0.286		0.210 (0.069, 0.351), 0.003	
AEs Related to Study Drug, n (%)	3 (9.4)	7 (13.5)	2 (5.7)	17 (23.9)	0.246
Odds Ratio (95% CIs) [1], P-Value		1.504 (0.360, 6.288), 0.574		5.194 (1.127, 23.937), 0.021	
Relative Risk (95% CIs) [2], P-Value		1.436 (0.400, 5.158), 0.579		4.190 (1.025, 17.131), 0.046	
Risk Difference (95% CIs) [2], P-Value		0.041 (-0.096, 0.178), 0.559		0.182 (0.057, 0.308), 0.004	
Serious AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.3a
Summary of All Adverse Events by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Oedema CMQ	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	P-Value [3]
Grade 1-2 AEs, n (%)	5 (15.6)	13 (25.0)	3 (8.6)	21 (29.6)	0.300
Odds Ratio (95% CIs) [1], P-Value		1.800 (0.574, 5.640), 0.309		4.480 (1.235, 16.251), 0.015	
Relative Risk (95% CIs) [2], P-Value		1.600 (0.630, 4.066), 0.323		3.451 (1.104, 10.789), 0.033	
Risk Difference (95% CIs) [2], P-Value		0.094 (-0.079, 0.266), 0.286		0.210 (0.069, 0.351), 0.003	
Grade 1-2 AEs Related to Study Drug, n (%)	3 (9.4)	7 (13.5)	2 (5.7)	17 (23.9)	0.246
Odds Ratio (95% CIs) [1], P-Value		1.504 (0.360, 6.288), 0.574		5.194 (1.127, 23.937), 0.021	
Relative Risk (95% CIs) [2], P-Value		1.436 (0.400, 5.158), 0.579		4.190 (1.025, 17.131), 0.046	
Risk Difference (95% CIs) [2], P-Value		0.041 (-0.096, 0.178), 0.559		0.182 (0.057, 0.308), 0.004	
Grade >=3 AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.3a
Summary of All Adverse Events by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Oedema CMQ	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	0	1 (1.9)	0	0	0.964
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.430		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.019 (-0.018, 0.057), 0.313		NA (NA, NA), NA	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	0	1 (1.9)	0	0	0.964
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.430		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.019 (-0.018, 0.057), 0.313		NA (NA, NA), NA	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Interruption of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.3a
Summary of All Adverse Events by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Oedema CMQ	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Overall	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Any AEs						
United States	23/27 (85.2)	39/44 (88.6)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	13/14 (92.9)	16/17 (94.1)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	3/3 (100.0)	13/13 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	5/5 (100.0)	9/10 (90.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	5/5 (100.0)	10/10 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	5/5 (100.0)	8/8 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	3/3 (100.0)	6/7 (85.7)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	2/2 (100.0)	5/5 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	1/1 (100.0)	2/2 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	2/3 (66.7)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	1/1 (100.0)	2/2 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	1/1 (100.0)	1/1 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	1/1 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Overall	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
AEs Related to Study Drug						
United States	12/27 (44.4)	23/44 (52.3)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	9/14 (64.3)	13/17 (76.5)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	8/13 (61.5)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	1/5 (20.0)	3/10 (30.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	3/5 (60.0)	5/10 (50.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	2/5 (40.0)	3/8 (37.5)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	1/3 (33.3)	2/7 (28.6)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	1/2 (50.0)	5/5 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	1/1 (100.0)	2/2 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	1/3 (33.3)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	1/1 (100.0)	2/2 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	1/1 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	1/1 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Overall	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Serious AEs						
United States	3/27 (11.1)	2/44 (4.5)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	2/14 (14.3)	0/17	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	1/3 (33.3)	0/13	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	1/5 (20.0)	2/10 (20.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	1/5 (20.0)	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/7	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	1/2 (50.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	1/2 (50.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Overall	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Serious AEs Related to Study Drug						
United States	0/27	0/44	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/14	0/17	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/13	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/7	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Overall	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Grade 1-2 AEs						
United States	22/27 (81.5)	39/44 (88.6)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	13/14 (92.9)	16/17 (94.1)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	3/3 (100.0)	13/13 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	5/5 (100.0)	9/10 (90.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	5/5 (100.0)	10/10 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	5/5 (100.0)	8/8 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	3/3 (100.0)	6/7 (85.7)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	2/2 (100.0)	5/5 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	1/1 (100.0)	2/2 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	2/3 (66.7)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	1/1 (100.0)	2/2 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	1/1 (100.0)	1/1 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	1/1 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Overall	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Grade 1-2 AEs Related to Study Drug						
United States	12/27 (44.4)	23/44 (52.3)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	9/14 (64.3)	13/17 (76.5)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	8/13 (61.5)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	1/5 (20.0)	3/10 (30.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	3/5 (60.0)	5/10 (50.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	2/5 (40.0)	3/8 (37.5)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	1/3 (33.3)	2/7 (28.6)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	1/2 (50.0)	5/5 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	1/1 (100.0)	2/2 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	1/3 (33.3)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	1/1 (100.0)	2/2 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	1/1 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	1/1 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Overall	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Grade >=3 AEs						
United States	6/27 (22.2)	10/44 (22.7)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	3/14 (21.4)	3/17 (17.6)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	1/3 (33.3)	4/13 (30.8)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	1/10 (10.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	2/5 (40.0)	2/10 (20.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	1/5 (20.0)	1/8 (12.5)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/7	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	1/5 (20.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	1/2 (50.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	1/3 (33.3)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	1/1 (100.0)	2/2 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Overall	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Grade >=3 AEs Related to Study Drug						
United States	1/27 (3.7)	1/44 (2.3)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/14	0/17	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/13	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/7	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	1/1 (100.0)	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Overall	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality						
United States	4/27 (14.8)	4/44 (9.1)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	2/14 (14.3)	1/17 (5.9)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/13	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	1/5 (20.0)	2/10 (20.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	1/5 (20.0)	1/8 (12.5)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	1/7 (14.3)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	1/2 (50.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	1/1 (100.0)	1/2 (50.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Overall	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
AEs Leading to Reduction of Study Drug Regardless of Causality						
United States	1/27 (3.7)	2/44 (4.5)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/14	0/17	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/13	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/7	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Overall	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality						
United States	0/27	0/44	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/14	0/17	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/13	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	1/7 (14.3)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	1/1 (100.0)	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Overall	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Related AEs Leading to Interruption of Study Drug						
United States	1/27 (3.7)	2/44 (4.5)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	1/14 (7.1)	0/17	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/13	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	1/5 (20.0)	1/8 (12.5)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	1/7 (14.3)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	1/1 (100.0)	1/2 (50.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Overall	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Related AEs Leading to Reduction of Study Drug						
United States	1/27 (3.7)	1/44 (2.3)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/14	0/17	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/13	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/7	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Overall	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Related AEs Leading to Permanent Discontinuation of Study Drug						
United States	0/27	0/44	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/14	0/17	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/13	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	1/7 (14.3)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	1/1 (100.0)	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Overall	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
AE leading to Death						
United States	0/27	0/44	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/14	0/17	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/13	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/7	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Cognitive Effects AESI	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Any AEs						
United States	2/27 (7.4)	2/44 (4.5)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/14	0/17	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	1/13 (7.7)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	1/5 (20.0)	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/7	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	1/2 (50.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Cognitive Effects AESI	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
AEs Related to Study Drug						
United States	1/27 (3.7)	1/44 (2.3)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/14	0/17	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	1/13 (7.7)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	1/5 (20.0)	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/7	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	1/2 (50.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Cognitive Effects AESI	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Serious AEs						
United States	1/27 (3.7)	0/44	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/14	0/17	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/13	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/7	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Cognitive Effects AESI	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Serious AEs Related to Study Drug						
United States	0/27	0/44	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/14	0/17	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/13	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/7	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Cognitive Effects AESI	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Grade 1-2 AEs						
United States	1/27 (3.7)	2/44 (4.5)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/14	0/17	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	1/13 (7.7)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	1/5 (20.0)	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/7	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	1/2 (50.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Cognitive Effects AESI	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Grade 1-2 AEs Related to Study Drug						
United States	1/27 (3.7)	1/44 (2.3)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/14	0/17	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	1/13 (7.7)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	1/5 (20.0)	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/7	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	1/2 (50.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Cognitive Effects AESI	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Grade >=3 AEs						
United States	1/27 (3.7)	0/44	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/14	0/17	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/13	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/7	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Cognitive Effects AESI	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Grade >=3 AEs Related to Study Drug						
United States	0/27	0/44	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/14	0/17	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/13	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/7	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Cognitive Effects AESI	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality						
United States	0/27	1/44 (2.3)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/14	0/17	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/13	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/7	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	1/2 (50.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Cognitive Effects AESI	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
AEs Leading to Reduction of Study Drug Regardless of Causality						
United States	1/27 (3.7)	1/44 (2.3)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/14	0/17	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/13	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/7	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Cognitive Effects AESI	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality						
United States	0/27	0/44	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/14	0/17	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/13	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/7	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Cognitive Effects AESI	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Related AEs Leading to Interruption of Study Drug						
United States	0/27	1/44 (2.3)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/14	0/17	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/13	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/7	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	1/2 (50.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Cognitive Effects AESI	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Related AEs Leading to Reduction of Study Drug						
United States	1/27 (3.7)	1/44 (2.3)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/14	0/17	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/13	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/7	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Cognitive Effects AESI	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Related AEs Leading to Permanent Discontinuation of Study Drug						
United States	0/27	0/44	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/14	0/17	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/13	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/7	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Cognitive Effects AESI	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
AE leading to Death						
United States	0/27	0/44	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/14	0/17	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/13	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/7	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Intracranial Bleeding AESI	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Any AEs						
United States	0/27	0/44	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/14	0/17	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/13	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/7	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Intracranial Bleeding AESI	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
AEs Related to Study Drug						
United States	0/27	0/44	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/14	0/17	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/13	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/7	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Intracranial Bleeding AESI	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Serious AEs						
United States	0/27	0/44	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/14	0/17	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/13	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/7	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Intracranial Bleeding AESI	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Serious AEs Related to Study Drug						
United States	0/27	0/44	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/14	0/17	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/13	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/7	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Intracranial Bleeding AESI	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Grade 1-2 AEs						
United States	0/27	0/44	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/14	0/17	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/13	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/7	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Intracranial Bleeding AESI	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Grade 1-2 AEs Related to Study Drug						
United States	0/27	0/44	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/14	0/17	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/13	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/7	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Intracranial Bleeding AESI	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Grade >=3 AEs						
United States	0/27	0/44	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/14	0/17	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/13	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/7	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Intracranial Bleeding AESI	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Grade >=3 AEs Related to Study Drug						
United States	0/27	0/44	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/14	0/17	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/13	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/7	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Intracranial Bleeding AESI	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality						
United States	0/27	0/44	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/14	0/17	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/13	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/7	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Intracranial Bleeding AESI	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
AEs Leading to Reduction of Study Drug Regardless of Causality						
United States	0/27	0/44	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/14	0/17	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/13	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/7	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Intracranial Bleeding AESI	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality						
United States	0/27	0/44	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/14	0/17	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/13	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/7	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Intracranial Bleeding AESI	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Related AEs Leading to Interruption of Study Drug						
United States	0/27	0/44	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/14	0/17	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/13	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/7	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Intracranial Bleeding AESI	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Related AEs Leading to Reduction of Study Drug						
United States	0/27	0/44	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/14	0/17	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/13	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/7	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Intracranial Bleeding AESI	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Related AEs Leading to Permanent Discontinuation of Study Drug						
United States	0/27	0/44	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/14	0/17	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/13	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/7	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Intracranial Bleeding AESI	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
AE leading to Death						
United States	0/27	0/44	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/14	0/17	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/13	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/7	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Oedema CMQ	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Any AEs						
United States	4/27 (14.8)	9/44 (20.5)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	1/14 (7.1)	4/17 (23.5)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	7/13 (53.8)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	2/10 (20.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	2/10 (20.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	1/5 (20.0)	4/8 (50.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	1/7 (14.3)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	2/5 (40.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	1/2 (50.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	1/3 (33.3)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	1/1 (100.0)	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	1/1 (100.0)	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	1/1 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Oedema CMQ	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
AEs Related to Study Drug						
United States	3/27 (11.1)	6/44 (13.6)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	1/14 (7.1)	3/17 (17.6)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	7/13 (53.8)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	2/10 (20.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	2/10 (20.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	1/8 (12.5)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/7	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	2/5 (40.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	1/1 (100.0)	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	1/1 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Oedema CMQ	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Serious AEs						
United States	0/27	0/44	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/14	0/17	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/13	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/7	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Oedema CMQ	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Serious AEs Related to Study Drug						
United States	0/27	0/44	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/14	0/17	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/13	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/7	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Oedema CMQ	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Grade 1-2 AEs						
United States	4/27 (14.8)	9/44 (20.5)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	1/14 (7.1)	4/17 (23.5)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	7/13 (53.8)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	2/10 (20.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	2/10 (20.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	1/5 (20.0)	4/8 (50.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	1/7 (14.3)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	2/5 (40.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	1/2 (50.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	1/3 (33.3)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	1/1 (100.0)	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	1/1 (100.0)	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	1/1 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Oedema CMQ	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Grade 1-2 AEs Related to Study Drug						
United States	3/27 (11.1)	6/44 (13.6)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	1/14 (7.1)	3/17 (17.6)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	7/13 (53.8)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	2/10 (20.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	2/10 (20.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	1/8 (12.5)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/7	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	2/5 (40.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	1/1 (100.0)	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	1/1 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Oedema CMQ	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Grade >=3 AEs						
United States	0/27	0/44	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/14	0/17	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/13	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/7	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Oedema CMQ	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Grade >=3 AEs Related to Study Drug						
United States	0/27	0/44	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/14	0/17	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/13	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/7	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Oedema CMQ	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality						
United States	0/27	1/44 (2.3)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/14	0/17	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/13	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/7	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Oedema CMQ	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
AEs Leading to Reduction of Study Drug Regardless of Causality						
United States	0/27	1/44 (2.3)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/14	0/17	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/13	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/7	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Oedema CMQ	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality						
United States	0/27	0/44	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/14	0/17	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/13	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/7	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Oedema CMQ	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Related AEs Leading to Interruption of Study Drug						
United States	0/27	0/44	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/14	0/17	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/13	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/7	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Oedema CMQ	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Related AEs Leading to Reduction of Study Drug						
United States	0/27	0/44	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/14	0/17	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/13	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/7	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Oedema CMQ	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Related AEs Leading to Permanent Discontinuation of Study Drug						
United States	0/27	0/44	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/14	0/17	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/13	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/7	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.9a
Summary of All Adverse Events by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

Oedema CMQ	Placebo (N=67) n/N n (%)	Ava 25 mg (N=123) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
AE leading to Death						
United States	0/27	0/44	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/14	0/17	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/13	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/10	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/7	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/2	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.1.2.4a
Summary of All Adverse Events by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Overall	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	P-Value [3]
Any AEs, n (%)	21 (95.5)	33 (89.2)	41 (91.1)	81 (94.2)	0.301
Odds Ratio (95% CIs) [1], P-Value		0.393 (0.041, 3.759), 0.403		1.580 (0.403, 6.204), 0.509	
Relative Risk (95% CIs) [2], P-Value		0.934 (0.809, 1.080), 0.357		1.034 (0.930, 1.149), 0.537	
Risk Difference (95% CIs) [2], P-Value		-0.063 (-0.195, 0.070), 0.354		0.031 (-0.066, 0.127), 0.533	
AEs Related to Study Drug, n (%)	11 (50.0)	16 (43.2)	20 (44.4)	53 (61.6)	0.140
Odds Ratio (95% CIs) [1], P-Value		0.762 (0.264, 2.197), 0.614		2.008 (0.966, 4.171), 0.060	
Relative Risk (95% CIs) [2], P-Value		0.865 (0.495, 1.510), 0.610		1.387 (0.961, 2.001), 0.081	
Risk Difference (95% CIs) [2], P-Value		-0.068 (-0.331, 0.195), 0.614		0.172 (-0.006, 0.350), 0.058	
Serious AEs, n (%)	3 (13.6)	0	5 (11.1)	6 (7.0)	0.961
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.021		0.600 (0.173, 2.086), 0.418	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.628 (0.203, 1.945), 0.420	
Risk Difference (95% CIs) [2], P-Value		-0.136 (-0.280, 0.007), 0.062		-0.041 (-0.148, 0.065), 0.446	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.4a
Summary of All Adverse Events by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Overall	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	P-Value [3]
Grade 1-2 AEs, n (%)	21 (95.5)	33 (89.2)	40 (88.9)	81 (94.2)	0.217
Odds Ratio (95% CIs) [1], P-Value		0.393 (0.041, 3.759), 0.403		2.025 (0.554, 7.402), 0.278	
Relative Risk (95% CIs) [2], P-Value		0.934 (0.809, 1.080), 0.357		1.060 (0.944, 1.190), 0.328	
Risk Difference (95% CIs) [2], P-Value		-0.063 (-0.195, 0.070), 0.354		0.053 (-0.051, 0.157), 0.320	
Grade 1-2 AEs Related to Study Drug, n (%)	11 (50.0)	16 (43.2)	20 (44.4)	53 (61.6)	0.140
Odds Ratio (95% CIs) [1], P-Value		0.762 (0.264, 2.197), 0.614		2.008 (0.966, 4.171), 0.060	
Relative Risk (95% CIs) [2], P-Value		0.865 (0.495, 1.510), 0.610		1.387 (0.961, 2.001), 0.081	
Risk Difference (95% CIs) [2], P-Value		-0.068 (-0.331, 0.195), 0.614		0.172 (-0.006, 0.350), 0.058	
Grade >=3 AEs, n (%)	5 (22.7)	7 (18.9)	9 (20.0)	19 (22.1)	0.655
Odds Ratio (95% CIs) [1], P-Value		0.793 (0.218, 2.890), 0.725		1.134 (0.466, 2.764), 0.781	
Relative Risk (95% CIs) [2], P-Value		0.832 (0.300, 2.307), 0.724		1.105 (0.545, 2.239), 0.782	
Risk Difference (95% CIs) [2], P-Value		-0.038 (-0.254, 0.178), 0.729		0.021 (-0.125, 0.167), 0.779	
Grade >=3 AEs Related to Study Drug, n (%)	1 (4.5)	0	1 (2.2)	1 (1.2)	0.957
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.191		0.518 (0.032, 8.475), 0.639	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.523 (0.034, 8.171), 0.644	
Risk Difference (95% CIs) [2], P-Value		-0.045 (-0.132, 0.042), 0.306		-0.011 (-0.059, 0.038), 0.670	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.4a
Summary of All Adverse Events by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Overall	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	5 (22.7)	1 (2.7)	4 (8.9)	10 (11.6)	0.040
Odds Ratio (95% CIs) [1], P-Value		0.094 (0.010, 0.872), 0.014		1.349 (0.398, 4.569), 0.630	
Relative Risk (95% CIs) [2], P-Value		0.119 (0.015, 0.953), 0.045		1.308 (0.435, 3.938), 0.633	
Risk Difference (95% CIs) [2], P-Value		-0.200 (-0.383, -0.018), 0.032		0.027 (-0.080, 0.135), 0.617	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	1 (4.5)	1 (2.7)	0	1 (1.2)	0.954
Odds Ratio (95% CIs) [1], P-Value		0.583 (0.035, 9.822), 0.705		NE (NE, NE), 0.468	
Relative Risk (95% CIs) [2], P-Value		0.595 (0.039, 9.036), 0.708		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.018 (-0.120, 0.083), 0.722		0.012 (-0.011, 0.034), 0.314	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	1 (4.5)	0	0	1 (1.2)	0.935
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.191		NE (NE, NE), 0.468	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.045 (-0.132, 0.042), 0.306		0.012 (-0.011, 0.034), 0.314	
Related AEs Leading to Interruption of Study Drug, n (%)	4 (18.2)	1 (2.7)	0	4 (4.7)	0.936
Odds Ratio (95% CIs) [1], P-Value		0.125 (0.013, 1.202), 0.039		NE (NE, NE), 0.142	
Relative Risk (95% CIs) [2], P-Value		0.149 (0.018, 1.247), 0.079		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.155 (-0.324, 0.015), 0.073		0.047 (0.002, 0.091), 0.041	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.4a
Summary of All Adverse Events by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Overall	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	1 (4.5)	1 (2.7)	0	0	>0.999
Odds Ratio (95% CIs) [1], P-Value		0.583 (0.035, 9.822), 0.705		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		0.595 (0.039, 9.036), 0.708		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.018 (-0.120, 0.083), 0.722		NA (NA, NA), NA	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	1 (4.5)	0	0	1 (1.2)	0.935
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.191		NE (NE, NE), 0.468	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.045 (-0.132, 0.042), 0.306		0.012 (-0.011, 0.034), 0.314	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.4a
Summary of All Adverse Events by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Cognitive Effects AESI	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	P-Value [3]
Any AEs, n (%)	2 (9.1)	1 (2.7)	1 (2.2)	3 (3.5)	0.309
Odds Ratio (95% CIs) [1], P-Value		0.278 (0.024, 3.258), 0.280		1.590 (0.161, 15.744), 0.689	
Relative Risk (95% CIs) [2], P-Value		0.297 (0.029, 3.092), 0.310		1.570 (0.168, 14.661), 0.692	
Risk Difference (95% CIs) [2], P-Value		-0.064 (-0.195, 0.067), 0.339		0.013 (-0.045, 0.071), 0.669	
AEs Related to Study Drug, n (%)	1 (4.5)	1 (2.7)	1 (2.2)	2 (2.3)	0.758
Odds Ratio (95% CIs) [1], P-Value		0.583 (0.035, 9.822), 0.705		1.048 (0.092, 11.876), 0.970	
Relative Risk (95% CIs) [2], P-Value		0.595 (0.039, 9.036), 0.708		1.047 (0.098, 11.231), 0.970	
Risk Difference (95% CIs) [2], P-Value		-0.018 (-0.120, 0.083), 0.722		0.001 (-0.053, 0.055), 0.970	
Serious AEs, n (%)	1 (4.5)	0	0	0	0.964
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.191		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.045 (-0.132, 0.042), 0.306		NA (NA, NA), NA	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.4a
Summary of All Adverse Events by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Cognitive Effects AESI	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	P-Value [3]
Grade 1-2 AEs, n (%)	1 (4.5)	1 (2.7)	1 (2.2)	3 (3.5)	0.589
Odds Ratio (95% CIs) [1], P-Value		0.583 (0.035, 9.822), 0.705		1.590 (0.161, 15.744), 0.689	
Relative Risk (95% CIs) [2], P-Value		0.595 (0.039, 9.036), 0.708		1.570 (0.168, 14.661), 0.692	
Risk Difference (95% CIs) [2], P-Value		-0.018 (-0.120, 0.083), 0.722		0.013 (-0.045, 0.071), 0.669	
Grade 1-2 AEs Related to Study Drug, n (%)	1 (4.5)	1 (2.7)	1 (2.2)	2 (2.3)	0.758
Odds Ratio (95% CIs) [1], P-Value		0.583 (0.035, 9.822), 0.705		1.048 (0.092, 11.876), 0.970	
Relative Risk (95% CIs) [2], P-Value		0.595 (0.039, 9.036), 0.708		1.047 (0.098, 11.231), 0.970	
Risk Difference (95% CIs) [2], P-Value		-0.018 (-0.120, 0.083), 0.722		0.001 (-0.053, 0.055), 0.970	
Grade >=3 AEs, n (%)	1 (4.5)	0	0	0	0.964
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.191		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.045 (-0.132, 0.042), 0.306		NA (NA, NA), NA	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.4a
Summary of All Adverse Events by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Cognitive Effects AESI	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	0	1 (2.7)	0	1 (1.2)	0.997
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.437		NE (NE, NE), 0.468	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.027 (-0.025, 0.079), 0.311		0.012 (-0.011, 0.034), 0.314	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	1 (4.5)	1 (2.7)	0	0	>0.999
Odds Ratio (95% CIs) [1], P-Value		0.583 (0.035, 9.822), 0.705		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		0.595 (0.039, 9.036), 0.708		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.018 (-0.120, 0.083), 0.722		NA (NA, NA), NA	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Interruption of Study Drug, n (%)	0	1 (2.7)	0	1 (1.2)	0.997
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.437		NE (NE, NE), 0.468	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.027 (-0.025, 0.079), 0.311		0.012 (-0.011, 0.034), 0.314	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-pp-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.1.2.4a
Summary of All Adverse Events by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Cognitive Effects AESI	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	1 (4.5)	1 (2.7)	0	0	>0.999
Odds Ratio (95% CIs) [1], P-Value		0.583 (0.035, 9.822), 0.705		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		0.595 (0.039, 9.036), 0.708		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.018 (-0.120, 0.083), 0.722		NA (NA, NA), NA	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.4a
Summary of All Adverse Events by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Intracranial Bleeding AESI	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	P-Value [3]
Any AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Serious AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.4a
Summary of All Adverse Events by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Intracranial Bleeding AESI	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	P-Value [3]
Grade 1-2 AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade 1-2 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade >=3 AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.4a
Summary of All Adverse Events by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Intracranial Bleeding AESI	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Interruption of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.4a
Summary of All Adverse Events by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Intracranial Bleeding AESI	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.4a
Summary of All Adverse Events by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Oedema CMQ	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	P-Value [3]
Any AEs, n (%)	2 (9.1)	8 (21.6)	6 (13.3)	26 (30.2)	0.983
Odds Ratio (95% CIs) [1], P-Value		2.759 (0.529, 14.377), 0.215		2.817 (1.062, 7.467), 0.033	
Relative Risk (95% CIs) [2], P-Value		2.378 (0.554, 10.209), 0.244		2.267 (1.008, 5.103), 0.048	
Risk Difference (95% CIs) [2], P-Value		0.125 (-0.054, 0.304), 0.170		0.169 (0.030, 0.308), 0.017	
AEs Related to Study Drug, n (%)	1 (4.5)	7 (18.9)	4 (8.9)	17 (19.8)	0.597
Odds Ratio (95% CIs) [1], P-Value		4.900 (0.560, 42.840), 0.119		2.525 (0.795, 8.021), 0.107	
Relative Risk (95% CIs) [2], P-Value		4.162 (0.548, 31.620), 0.168		2.224 (0.796, 6.215), 0.127	
Risk Difference (95% CIs) [2], P-Value		0.144 (-0.010, 0.297), 0.066		0.109 (-0.010, 0.227), 0.072	
Serious AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.4a
Summary of All Adverse Events by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Oedema CMQ	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	P-Value [3]
Grade 1-2 AEs, n (%)	2 (9.1)	8 (21.6)	6 (13.3)	26 (30.2)	0.983
Odds Ratio (95% CIs) [1], P-Value		2.759 (0.529, 14.377), 0.215		2.817 (1.062, 7.467), 0.033	
Relative Risk (95% CIs) [2], P-Value		2.378 (0.554, 10.209), 0.244		2.267 (1.008, 5.103), 0.048	
Risk Difference (95% CIs) [2], P-Value		0.125 (-0.054, 0.304), 0.170		0.169 (0.030, 0.308), 0.017	
Grade 1-2 AEs Related to Study Drug, n (%)	1 (4.5)	7 (18.9)	4 (8.9)	17 (19.8)	0.597
Odds Ratio (95% CIs) [1], P-Value		4.900 (0.560, 42.840), 0.119		2.525 (0.795, 8.021), 0.107	
Relative Risk (95% CIs) [2], P-Value		4.162 (0.548, 31.620), 0.168		2.224 (0.796, 6.215), 0.127	
Risk Difference (95% CIs) [2], P-Value		0.144 (-0.010, 0.297), 0.066		0.109 (-0.010, 0.227), 0.072	
Grade >=3 AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.4a
Summary of All Adverse Events by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Oedema CMQ	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	0	0	0	1 (1.2)	0.970
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.468	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.012 (-0.011, 0.034), 0.314	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	0	0	0	1 (1.2)	0.970
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.468	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.012 (-0.011, 0.034), 0.314	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Interruption of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.4a
Summary of All Adverse Events by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Oedema CMQ	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.5a
Summary of All Adverse Events by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Overall	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	P-Value [3]
Any AEs, n (%)	12 (92.3)	25 (96.2)	50 (92.6)	89 (91.8)	0.593
Odds Ratio (95% CIs) [1], P-Value		2.083 (0.120, 36.233), 0.608		0.890 (0.255, 3.104), 0.855	
Relative Risk (95% CIs) [2], P-Value		1.042 (0.875, 1.241), 0.647		0.991 (0.900, 1.091), 0.853	
Risk Difference (95% CIs) [2], P-Value		0.038 (-0.124, 0.201), 0.643		-0.008 (-0.097, 0.080), 0.853	
AEs Related to Study Drug, n (%)	6 (46.2)	9 (34.6)	25 (46.3)	60 (61.9)	0.150
Odds Ratio (95% CIs) [1], P-Value		0.618 (0.159, 2.400), 0.485		1.881 (0.959, 3.690), 0.065	
Relative Risk (95% CIs) [2], P-Value		0.750 (0.340, 1.652), 0.475		1.336 (0.963, 1.853), 0.082	
Risk Difference (95% CIs) [2], P-Value		-0.115 (-0.442, 0.212), 0.489		0.156 (-0.009, 0.320), 0.064	
Serious AEs, n (%)	1 (7.7)	3 (11.5)	7 (13.0)	3 (3.1)	0.156
Odds Ratio (95% CIs) [1], P-Value		1.565 (0.147, 16.716), 0.709		0.214 (0.053, 0.866), 0.019	
Relative Risk (95% CIs) [2], P-Value		1.500 (0.172, 13.046), 0.713		0.239 (0.064, 0.885), 0.032	
Risk Difference (95% CIs) [2], P-Value		0.038 (-0.151, 0.228), 0.691		-0.099 (-0.195, -0.003), 0.044	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.5a
Summary of All Adverse Events by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Overall	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	P-Value [3]
Grade 1-2 AEs, n (%)	12 (92.3)	25 (96.2)	49 (90.7)	89 (91.8)	0.700
Odds Ratio (95% CIs) [1], P-Value		2.083 (0.120, 36.233), 0.608		1.135 (0.352, 3.659), 0.832	
Relative Risk (95% CIs) [2], P-Value		1.042 (0.875, 1.241), 0.647		1.011 (0.911, 1.122), 0.834	
Risk Difference (95% CIs) [2], P-Value		0.038 (-0.124, 0.201), 0.643		0.010 (-0.085, 0.105), 0.834	
Grade 1-2 AEs Related to Study Drug, n (%)	6 (46.2)	9 (34.6)	25 (46.3)	60 (61.9)	0.150
Odds Ratio (95% CIs) [1], P-Value		0.618 (0.159, 2.400), 0.485		1.881 (0.959, 3.690), 0.065	
Relative Risk (95% CIs) [2], P-Value		0.750 (0.340, 1.652), 0.475		1.336 (0.963, 1.853), 0.082	
Risk Difference (95% CIs) [2], P-Value		-0.115 (-0.442, 0.212), 0.489		0.156 (-0.009, 0.320), 0.064	
Grade >=3 AEs, n (%)	1 (7.7)	12 (46.2)	13 (24.1)	14 (14.4)	0.013
Odds Ratio (95% CIs) [1], P-Value		10.286 (1.162, 91.068), 0.016		0.532 (0.229, 1.235), 0.138	
Relative Risk (95% CIs) [2], P-Value		6.000 (0.872, 41.267), 0.069		0.600 (0.304, 1.181), 0.139	
Risk Difference (95% CIs) [2], P-Value		0.385 (0.144, 0.625), 0.002		-0.096 (-0.230, 0.037), 0.158	
Grade >=3 AEs Related to Study Drug, n (%)	1 (7.7)	0	1 (1.9)	1 (1.0)	0.972
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.152		0.552 (0.034, 9.007), 0.672	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.557 (0.036, 8.724), 0.677	
Risk Difference (95% CIs) [2], P-Value		-0.077 (-0.222, 0.068), 0.298		-0.008 (-0.049, 0.033), 0.696	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.5a
Summary of All Adverse Events by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Overall	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	1 (7.7)	2 (7.7)	8 (14.8)	9 (9.3)	0.700
Odds Ratio (95% CIs) [1], P-Value		1.000 (0.082, 12.164), >0.999		0.588 (0.213, 1.626), 0.302	
Relative Risk (95% CIs) [2], P-Value		1.000 (0.100, 10.037), >0.999		0.626 (0.257, 1.529), 0.304	
Risk Difference (95% CIs) [2], P-Value		0.000 (-0.177, 0.177), >0.999		-0.055 (-0.166, 0.056), 0.328	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	1 (7.7)	0	0	2 (2.1)	0.927
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.152		NE (NE, NE), 0.288	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.077 (-0.222, 0.068), 0.298		0.021 (-0.008, 0.049), 0.153	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	1 (1.9)	1 (1.0)	0.998
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.552 (0.034, 9.007), 0.672	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.557 (0.036, 8.724), 0.677	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.008 (-0.049, 0.033), 0.696	
Related AEs Leading to Interruption of Study Drug, n (%)	1 (7.7)	0	3 (5.6)	5 (5.2)	0.959
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.152		0.924 (0.212, 4.025), 0.916	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.928 (0.231, 3.733), 0.916	
Risk Difference (95% CIs) [2], P-Value		-0.077 (-0.222, 0.068), 0.298		-0.004 (-0.079, 0.071), 0.917	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.5a
Summary of All Adverse Events by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Overall	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	1 (7.7)	0	0	1 (1.0)	0.928
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.152		NE (NE, NE), 0.454	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.077 (-0.222, 0.068), 0.298		0.010 (-0.010, 0.030), 0.315	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	1 (1.9)	1 (1.0)	0.998
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.552 (0.034, 9.007), 0.672	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.557 (0.036, 8.724), 0.677	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.008 (-0.049, 0.033), 0.696	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.5a
Summary of All Adverse Events by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Cognitive Effects AESI	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	P-Value [3]
Any AEs, n (%)	1 (7.7)	0	2 (3.7)	4 (4.1)	0.962
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.152		1.118 (0.198, 6.314), 0.899	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.113 (0.211, 5.882), 0.899	
Risk Difference (95% CIs) [2], P-Value		-0.077 (-0.222, 0.068), 0.298		0.004 (-0.060, 0.068), 0.898	
AEs Related to Study Drug, n (%)	1 (7.7)	0	1 (1.9)	3 (3.1)	0.966
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.152		1.691 (0.172, 16.671), 0.649	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.670 (0.178, 15.665), 0.653	
Risk Difference (95% CIs) [2], P-Value		-0.077 (-0.222, 0.068), 0.298		0.012 (-0.037, 0.062), 0.625	
Serious AEs, n (%)	0	0	1 (1.9)	0	0.972
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.179	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.019 (-0.054, 0.017), 0.313	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.5a
Summary of All Adverse Events by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Cognitive Effects AESI	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	P-Value [3]
Grade 1-2 AEs, n (%)	1 (7.7)	0	1 (1.9)	4 (4.1)	0.963
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.152		2.280 (0.248, 20.928), 0.455	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		2.227 (0.255, 19.423), 0.469	
Risk Difference (95% CIs) [2], P-Value		-0.077 (-0.222, 0.068), 0.298		0.023 (-0.031, 0.076), 0.405	
Grade 1-2 AEs Related to Study Drug, n (%)	1 (7.7)	0	1 (1.9)	3 (3.1)	0.966
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.152		1.691 (0.172, 16.671), 0.649	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.670 (0.178, 15.665), 0.653	
Risk Difference (95% CIs) [2], P-Value		-0.077 (-0.222, 0.068), 0.298		0.012 (-0.037, 0.062), 0.625	
Grade >=3 AEs, n (%)	0	0	1 (1.9)	0	0.972
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.179	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.019 (-0.054, 0.017), 0.313	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.5a
Summary of All Adverse Events by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Cognitive Effects AESI	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	0	0	0	2 (2.1)	0.976
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.288	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.021 (-0.008, 0.049), 0.153	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	1 (7.7)	0	0	1 (1.0)	0.928
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.152		NE (NE, NE), 0.454	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.077 (-0.222, 0.068), 0.298		0.010 (-0.010, 0.030), 0.315	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Interruption of Study Drug, n (%)	0	0	0	2 (2.1)	0.976
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.288	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.021 (-0.008, 0.049), 0.153	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.5a
Summary of All Adverse Events by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Cognitive Effects AESI	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	1 (7.7)	0	0	1 (1.0)	0.928
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.152		NE (NE, NE), 0.454	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.077 (-0.222, 0.068), 0.298		0.010 (-0.010, 0.030), 0.315	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.5a
Summary of All Adverse Events by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Intracranial Bleeding AESI	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	P-Value [3]
Any AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Serious AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.5a
Summary of All Adverse Events by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Intracranial Bleeding AESI	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	P-Value [3]
Grade 1-2 AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade 1-2 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade >=3 AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.5a
Summary of All Adverse Events by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Intracranial Bleeding AESI	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Interruption of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.5a
Summary of All Adverse Events by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Intracranial Bleeding AESI	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.5a
Summary of All Adverse Events by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Oedema CMQ	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	P-Value [3]
Any AEs, n (%)	2 (15.4)	6 (23.1)	6 (11.1)	28 (28.9)	0.508
Odds Ratio (95% CIs) [1], P-Value		1.650 (0.283, 9.603), 0.575		3.246 (1.249, 8.441), 0.012	
Relative Risk (95% CIs) [2], P-Value		1.500 (0.350, 6.428), 0.585		2.598 (1.148, 5.878), 0.022	
Risk Difference (95% CIs) [2], P-Value		0.077 (-0.177, 0.331), 0.553		0.178 (0.054, 0.301), 0.005	
AEs Related to Study Drug, n (%)	1 (7.7)	2 (7.7)	4 (7.4)	22 (22.7)	0.353
Odds Ratio (95% CIs) [1], P-Value		1.000 (0.082, 12.164), >0.999		3.667 (1.192, 11.281), 0.017	
Relative Risk (95% CIs) [2], P-Value		1.000 (0.100, 10.037), >0.999		3.062 (1.113, 8.424), 0.030	
Risk Difference (95% CIs) [2], P-Value		0.000 (-0.177, 0.177), >0.999		0.153 (0.044, 0.261), 0.006	
Serious AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.5a
Summary of All Adverse Events by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Oedema CMQ	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	P-Value [3]
Grade 1-2 AEs, n (%)	2 (15.4)	6 (23.1)	6 (11.1)	28 (28.9)	0.508
Odds Ratio (95% CIs) [1], P-Value		1.650 (0.283, 9.603), 0.575		3.246 (1.249, 8.441), 0.012	
Relative Risk (95% CIs) [2], P-Value		1.500 (0.350, 6.428), 0.585		2.598 (1.148, 5.878), 0.022	
Risk Difference (95% CIs) [2], P-Value		0.077 (-0.177, 0.331), 0.553		0.178 (0.054, 0.301), 0.005	
Grade 1-2 AEs Related to Study Drug, n (%)	1 (7.7)	2 (7.7)	4 (7.4)	22 (22.7)	0.353
Odds Ratio (95% CIs) [1], P-Value		1.000 (0.082, 12.164), >0.999		3.667 (1.192, 11.281), 0.017	
Relative Risk (95% CIs) [2], P-Value		1.000 (0.100, 10.037), >0.999		3.062 (1.113, 8.424), 0.030	
Risk Difference (95% CIs) [2], P-Value		0.000 (-0.177, 0.177), >0.999		0.153 (0.044, 0.261), 0.006	
Grade >=3 AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.5a
Summary of All Adverse Events by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Oedema CMQ	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	0	0	0	1 (1.0)	0.975
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.454	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.010 (-0.010, 0.030), 0.315	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	0	0	0	1 (1.0)	0.975
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.454	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.010 (-0.010, 0.030), 0.315	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Interruption of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.5a
Summary of All Adverse Events by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Oedema CMQ	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.6a
Summary of All Adverse Events by Baseline Best Supportive Care
Per Protocol Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Overall	Placebo (N=32)	Avapritinib 25 mg (N=63)	Placebo (N=35)	Avapritinib 25 mg (N=60)	P-Value [3]
Any AEs, n (%)	29 (90.6)	57 (90.5)	33 (94.3)	57 (95.0)	0.895
Odds Ratio (95% CIs) [1], P-Value		0.983 (0.229, 4.216), 0.981		1.152 (0.183, 7.249), 0.880	
Relative Risk (95% CIs) [2], P-Value		0.998 (0.870, 1.145), 0.981		1.008 (0.912, 1.114), 0.883	
Risk Difference (95% CIs) [2], P-Value		-0.001 (-0.126, 0.123), 0.981		0.007 (-0.087, 0.102), 0.882	
AEs Related to Study Drug, n (%)	16 (50.0)	40 (63.5)	15 (42.9)	29 (48.3)	0.588
Odds Ratio (95% CIs) [1], P-Value		1.739 (0.734, 4.119), 0.206		1.247 (0.539, 2.887), 0.606	
Relative Risk (95% CIs) [2], P-Value		1.270 (0.856, 1.883), 0.234		1.128 (0.709, 1.793), 0.611	
Risk Difference (95% CIs) [2], P-Value		0.135 (-0.075, 0.345), 0.208		0.055 (-0.152, 0.262), 0.604	
Serious AEs, n (%)	2 (6.3)	1 (1.6)	6 (17.1)	5 (8.3)	0.671
Odds Ratio (95% CIs) [1], P-Value		0.242 (0.021, 2.775), 0.219		0.439 (0.123, 1.563), 0.196	
Relative Risk (95% CIs) [2], P-Value		0.254 (0.024, 2.696), 0.256		0.486 (0.160, 1.477), 0.203	
Risk Difference (95% CIs) [2], P-Value		-0.047 (-0.136, 0.043), 0.306		-0.088 (-0.231, 0.055), 0.228	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.6a
Summary of All Adverse Events by Baseline Best Supportive Care
Per Protocol Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Overall	Placebo (N=32)	Avapritinib 25 mg (N=63)	Placebo (N=35)	Avapritinib 25 mg (N=60)	P-Value [3]
Grade 1-2 AEs, n (%)	29 (90.6)	57 (90.5)	32 (91.4)	57 (95.0)	0.597
Odds Ratio (95% CIs) [1], P-Value		0.983 (0.229, 4.216), 0.981		1.781 (0.339, 9.348), 0.490	
Relative Risk (95% CIs) [2], P-Value		0.998 (0.870, 1.145), 0.981		1.039 (0.924, 1.168), 0.520	
Risk Difference (95% CIs) [2], P-Value		-0.001 (-0.126, 0.123), 0.981		0.036 (-0.072, 0.144), 0.517	
Grade 1-2 AEs Related to Study Drug, n (%)	16 (50.0)	40 (63.5)	15 (42.9)	29 (48.3)	0.588
Odds Ratio (95% CIs) [1], P-Value		1.739 (0.734, 4.119), 0.206		1.247 (0.539, 2.887), 0.606	
Relative Risk (95% CIs) [2], P-Value		1.270 (0.856, 1.883), 0.234		1.128 (0.709, 1.793), 0.611	
Risk Difference (95% CIs) [2], P-Value		0.135 (-0.075, 0.345), 0.208		0.055 (-0.152, 0.262), 0.604	
Grade >=3 AEs, n (%)	5 (15.6)	10 (15.9)	9 (25.7)	16 (26.7)	0.968
Odds Ratio (95% CIs) [1], P-Value		1.019 (0.316, 3.280), 0.975		1.051 (0.406, 2.716), 0.919	
Relative Risk (95% CIs) [2], P-Value		1.016 (0.379, 2.722), 0.975		1.037 (0.514, 2.093), 0.919	
Risk Difference (95% CIs) [2], P-Value		0.002 (-0.152, 0.157), 0.975		0.010 (-0.173, 0.193), 0.919	
Grade >=3 AEs Related to Study Drug, n (%)	1 (3.1)	1 (1.6)	1 (2.9)	0	0.948
Odds Ratio (95% CIs) [1], P-Value		0.500 (0.030, 8.265), 0.622		NE (NE, NE), 0.188	
Relative Risk (95% CIs) [2], P-Value		0.508 (0.033, 7.858), 0.628		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.015 (-0.083, 0.052), 0.656		-0.029 (-0.084, 0.027), 0.310	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.6a
Summary of All Adverse Events by Baseline Best Supportive Care
Per Protocol Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Overall	Placebo (N=32)	Avapritinib 25 mg (N=63)	Placebo (N=35)	Avapritinib 25 mg (N=60)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	3 (9.4)	4 (6.3)	6 (17.1)	7 (11.7)	0.979
Odds Ratio (95% CIs) [1], P-Value		0.655 (0.138, 3.124), 0.594		0.638 (0.196, 2.079), 0.454	
Relative Risk (95% CIs) [2], P-Value		0.677 (0.161, 2.845), 0.595		0.681 (0.248, 1.864), 0.454	
Risk Difference (95% CIs) [2], P-Value		-0.030 (-0.148, 0.087), 0.614		-0.055 (-0.204, 0.094), 0.471	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	0	0	1 (2.9)	2 (3.3)	>0.999
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		1.172 (0.102, 13.418), 0.898	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		1.167 (0.110, 12.405), 0.898	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.005 (-0.067, 0.076), 0.896	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	1 (1.6)	1 (2.9)	0	0.920
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.474		NE (NE, NE), 0.188	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.016 (-0.015, 0.047), 0.313		-0.029 (-0.084, 0.027), 0.310	
Related AEs Leading to Interruption of Study Drug, n (%)	1 (3.1)	2 (3.2)	3 (8.6)	3 (5.0)	0.693
Odds Ratio (95% CIs) [1], P-Value		1.016 (0.089, 11.650), 0.990		0.561 (0.107, 2.946), 0.490	
Relative Risk (95% CIs) [2], P-Value		1.016 (0.096, 10.785), 0.990		0.583 (0.124, 2.735), 0.494	
Risk Difference (95% CIs) [2], P-Value		0.000 (-0.074, 0.075), 0.990		-0.036 (-0.144, 0.072), 0.517	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.6a
Summary of All Adverse Events by Baseline Best Supportive Care
Per Protocol Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Overall	Placebo (N=32)	Avapritinib 25 mg (N=63)	Placebo (N=35)	Avapritinib 25 mg (N=60)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	0	0	1 (2.9)	1 (1.7)	0.998
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.576 (0.035, 9.512), 0.697	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.583 (0.038, 9.037), 0.700	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.012 (-0.076, 0.052), 0.715	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	1 (1.6)	1 (2.9)	0	0.920
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.474		NE (NE, NE), 0.188	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.016 (-0.015, 0.047), 0.313		-0.029 (-0.084, 0.027), 0.310	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.6a
Summary of All Adverse Events by Baseline Best Supportive Care
Per Protocol Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Cognitive Effects AESI	Placebo (N=32)	Avapritinib 25 mg (N=63)	Placebo (N=35)	Avapritinib 25 mg (N=60)	P-Value [3]
Any AEs, n (%)	0	0	3 (8.6)	4 (6.7)	0.999
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.762 (0.160, 3.621), 0.732	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.778 (0.185, 3.275), 0.732	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.019 (-0.131, 0.093), 0.739	
AEs Related to Study Drug, n (%)	0	0	2 (5.7)	3 (5.0)	>0.999
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.868 (0.138, 5.467), 0.880	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.875 (0.154, 4.985), 0.880	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.007 (-0.102, 0.087), 0.882	
Serious AEs, n (%)	0	0	1 (2.9)	0	0.957
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.188	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.029 (-0.084, 0.027), 0.310	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.6a
Summary of All Adverse Events by Baseline Best Supportive Care
Per Protocol Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Cognitive Effects AESI	Placebo (N=32)	Avapritinib 25 mg (N=63)	Placebo (N=35)	Avapritinib 25 mg (N=60)	P-Value [3]
Grade 1-2 AEs, n (%)	0	0	2 (5.7)	4 (6.7)	>0.999
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		1.179 (0.205, 6.789), 0.854	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		1.167 (0.225, 6.047), 0.854	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.010 (-0.090, 0.109), 0.851	
Grade 1-2 AEs Related to Study Drug, n (%)	0	0	2 (5.7)	3 (5.0)	>0.999
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.868 (0.138, 5.467), 0.880	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.875 (0.154, 4.985), 0.880	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.007 (-0.102, 0.087), 0.882	
Grade >=3 AEs, n (%)	0	0	1 (2.9)	0	0.957
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.188	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.029 (-0.084, 0.027), 0.310	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.6a
Summary of All Adverse Events by Baseline Best Supportive Care
Per Protocol Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Cognitive Effects AESI	Placebo (N=32)	Avapritinib 25 mg (N=63)	Placebo (N=35)	Avapritinib 25 mg (N=60)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	0	0	0	2 (3.3)	0.966
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.275	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.033 (-0.012, 0.079), 0.150	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	0	0	1 (2.9)	1 (1.7)	0.998
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.576 (0.035, 9.512), 0.697	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.583 (0.038, 9.037), 0.700	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.012 (-0.076, 0.052), 0.715	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Interruption of Study Drug, n (%)	0	0	0	2 (3.3)	0.966
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.275	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.033 (-0.012, 0.079), 0.150	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.6a
Summary of All Adverse Events by Baseline Best Supportive Care
Per Protocol Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Cognitive Effects AESI	Placebo (N=32)	Avapritinib 25 mg (N=63)	Placebo (N=35)	Avapritinib 25 mg (N=60)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	0	0	1 (2.9)	1 (1.7)	0.998
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.576 (0.035, 9.512), 0.697	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.583 (0.038, 9.037), 0.700	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.012 (-0.076, 0.052), 0.715	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.6a
Summary of All Adverse Events by Baseline Best Supportive Care
Per Protocol Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Intracranial Bleeding AESI	Placebo (N=32)	Avapritinib 25 mg (N=63)	Placebo (N=35)	Avapritinib 25 mg (N=60)	P-Value [3]
Any AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Serious AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.6a
Summary of All Adverse Events by Baseline Best Supportive Care
Per Protocol Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Intracranial Bleeding AESI	Placebo (N=32)	Avapritinib 25 mg (N=63)	Placebo (N=35)	Avapritinib 25 mg (N=60)	P-Value [3]
Grade 1-2 AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade 1-2 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade >=3 AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.6a
Summary of All Adverse Events by Baseline Best Supportive Care
Per Protocol Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Intracranial Bleeding AESI	Placebo (N=32)	Avapritinib 25 mg (N=63)	Placebo (N=35)	Avapritinib 25 mg (N=60)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Interruption of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.6a
Summary of All Adverse Events by Baseline Best Supportive Care
Per Protocol Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Intracranial Bleeding AESI	Placebo (N=32)	Avapritinib 25 mg (N=63)	Placebo (N=35)	Avapritinib 25 mg (N=60)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.6a
Summary of All Adverse Events by Baseline Best Supportive Care
Per Protocol Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Oedema CMQ	Placebo (N=32)	Avapritinib 25 mg (N=63)	Placebo (N=35)	Avapritinib 25 mg (N=60)	P-Value [3]
Any AEs, n (%)	2 (6.3)	16 (25.4)	6 (17.1)	18 (30.0)	0.341
Odds Ratio (95% CIs) [1], P-Value		5.106 (1.095, 23.811), 0.024		2.071 (0.734, 5.849), 0.164	
Relative Risk (95% CIs) [2], P-Value		4.063 (0.995, 16.595), 0.051		1.750 (0.767, 3.991), 0.183	
Risk Difference (95% CIs) [2], P-Value		0.191 (0.055, 0.328), 0.006		0.129 (-0.042, 0.299), 0.139	
AEs Related to Study Drug, n (%)	1 (3.1)	11 (17.5)	4 (11.4)	13 (21.7)	0.365
Odds Ratio (95% CIs) [1], P-Value		6.558 (0.807, 53.277), 0.047		2.144 (0.640, 7.181), 0.209	
Relative Risk (95% CIs) [2], P-Value		5.587 (0.754, 41.385), 0.092		1.896 (0.670, 5.365), 0.228	
Risk Difference (95% CIs) [2], P-Value		0.143 (0.032, 0.255), 0.012		0.102 (-0.046, 0.251), 0.176	
Serious AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.6a
Summary of All Adverse Events by Baseline Best Supportive Care
Per Protocol Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Oedema CMQ	Placebo (N=32)	Avapritinib 25 mg (N=63)	Placebo (N=35)	Avapritinib 25 mg (N=60)	P-Value [3]
Grade 1-2 AEs, n (%)	2 (6.3)	16 (25.4)	6 (17.1)	18 (30.0)	0.341
Odds Ratio (95% CIs) [1], P-Value		5.106 (1.095, 23.811), 0.024		2.071 (0.734, 5.849), 0.164	
Relative Risk (95% CIs) [2], P-Value		4.063 (0.995, 16.595), 0.051		1.750 (0.767, 3.991), 0.183	
Risk Difference (95% CIs) [2], P-Value		0.191 (0.055, 0.328), 0.006		0.129 (-0.042, 0.299), 0.139	
Grade 1-2 AEs Related to Study Drug, n (%)	1 (3.1)	11 (17.5)	4 (11.4)	13 (21.7)	0.365
Odds Ratio (95% CIs) [1], P-Value		6.558 (0.807, 53.277), 0.047		2.144 (0.640, 7.181), 0.209	
Relative Risk (95% CIs) [2], P-Value		5.587 (0.754, 41.385), 0.092		1.896 (0.670, 5.365), 0.228	
Risk Difference (95% CIs) [2], P-Value		0.143 (0.032, 0.255), 0.012		0.102 (-0.046, 0.251), 0.176	
Grade >=3 AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.6a
Summary of All Adverse Events by Baseline Best Supportive Care
Per Protocol Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Oedema CMQ	Placebo (N=32)	Avapritinib 25 mg (N=63)	Placebo (N=35)	Avapritinib 25 mg (N=60)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	0	0	0	1 (1.7)	0.965
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.443	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.017 (-0.016, 0.049), 0.313	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	0	0	0	1 (1.7)	0.965
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.443	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.017 (-0.016, 0.049), 0.313	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Interruption of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.6a
Summary of All Adverse Events by Baseline Best Supportive Care
Per Protocol Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Oedema CMQ	Placebo (N=32)	Avapritinib 25 mg (N=63)	Placebo (N=35)	Avapritinib 25 mg (N=60)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.7a
Summary of All Adverse Events by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Overall	Placebo (N=6)	Avapritinib 25 mg (N=19)	Placebo (N=61)	Avapritinib 25 mg (N=104)	P-Value [3]
Any AEs, n (%)	6 (100.0)	16 (84.2)	56 (91.8)	98 (94.2)	0.960
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.299		1.458 (0.426, 4.996), 0.546	
Relative Risk (95% CIs) [2], P-Value		0.842 (0.693, 1.023), 0.084		1.026 (0.939, 1.122), 0.565	
Risk Difference (95% CIs) [2], P-Value		-0.158 (-0.322, 0.006), 0.059		0.024 (-0.058, 0.106), 0.562	
AEs Related to Study Drug, n (%)	1 (16.7)	8 (42.1)	30 (49.2)	61 (58.7)	0.461
Odds Ratio (95% CIs) [1], P-Value		3.636 (0.353, 37.457), 0.258		1.466 (0.776, 2.768), 0.238	
Relative Risk (95% CIs) [2], P-Value		2.526 (0.391, 16.314), 0.330		1.193 (0.882, 1.613), 0.253	
Risk Difference (95% CIs) [2], P-Value		0.254 (-0.117, 0.626), 0.180		0.095 (-0.062, 0.252), 0.237	
Serious AEs, n (%)	1 (16.7)	2 (10.5)	7 (11.5)	4 (3.8)	0.662
Odds Ratio (95% CIs) [1], P-Value		0.588 (0.044, 7.914), 0.687		0.309 (0.086, 1.101), 0.058	
Relative Risk (95% CIs) [2], P-Value		0.632 (0.069, 5.804), 0.685		0.335 (0.102, 1.099), 0.071	
Risk Difference (95% CIs) [2], P-Value		-0.061 (-0.390, 0.267), 0.714		-0.076 (-0.164, 0.012), 0.090	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.7a
Summary of All Adverse Events by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Overall	Placebo (N=6)	Avapritinib 25 mg (N=19)	Placebo (N=61)	Avapritinib 25 mg (N=104)	P-Value [3]
Grade 1-2 AEs, n (%)	5 (83.3)	16 (84.2)	56 (91.8)	98 (94.2)	0.825
Odds Ratio (95% CIs) [1], P-Value		1.067 (0.090, 12.686), 0.959		1.458 (0.426, 4.996), 0.546	
Relative Risk (95% CIs) [2], P-Value		1.011 (0.672, 1.519), 0.960		1.026 (0.939, 1.122), 0.565	
Risk Difference (95% CIs) [2], P-Value		0.009 (-0.332, 0.349), 0.960		0.024 (-0.058, 0.106), 0.562	
Grade 1-2 AEs Related to Study Drug, n (%)	1 (16.7)	8 (42.1)	30 (49.2)	61 (58.7)	0.461
Odds Ratio (95% CIs) [1], P-Value		3.636 (0.353, 37.457), 0.258		1.466 (0.776, 2.768), 0.238	
Relative Risk (95% CIs) [2], P-Value		2.526 (0.391, 16.314), 0.330		1.193 (0.882, 1.613), 0.253	
Risk Difference (95% CIs) [2], P-Value		0.254 (-0.117, 0.626), 0.180		0.095 (-0.062, 0.252), 0.237	
Grade >=3 AEs, n (%)	2 (33.3)	4 (21.1)	12 (19.7)	22 (21.2)	0.516
Odds Ratio (95% CIs) [1], P-Value		0.533 (0.070, 4.038), 0.539		1.096 (0.499, 2.408), 0.820	
Relative Risk (95% CIs) [2], P-Value		0.632 (0.151, 2.633), 0.528		1.075 (0.574, 2.016), 0.821	
Risk Difference (95% CIs) [2], P-Value		-0.123 (-0.542, 0.297), 0.566		0.015 (-0.112, 0.142), 0.819	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	2 (3.3)	1 (1.0)	0.995
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.286 (0.025, 3.226), 0.282	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.293 (0.027, 3.167), 0.312	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.023 (-0.072, 0.025), 0.349	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.7a
Summary of All Adverse Events by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Overall	Placebo (N=6)	Avapritinib 25 mg (N=19)	Placebo (N=61)	Avapritinib 25 mg (N=104)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	1 (16.7)	2 (10.5)	8 (13.1)	9 (8.7)	0.964
Odds Ratio (95% CIs) [1], P-Value		0.588 (0.044, 7.914), 0.687		0.628 (0.229, 1.723), 0.363	
Relative Risk (95% CIs) [2], P-Value		0.632 (0.069, 5.804), 0.685		0.660 (0.269, 1.620), 0.364	
Risk Difference (95% CIs) [2], P-Value		-0.061 (-0.390, 0.267), 0.714		-0.045 (-0.145, 0.056), 0.384	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	0	0	1 (1.6)	2 (1.9)	>0.999
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		1.176 (0.104, 13.251), 0.895	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		1.173 (0.109, 12.669), 0.895	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.003 (-0.039, 0.044), 0.893	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	1 (1.6)	1 (1.0)	0.998
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.583 (0.036, 9.484), 0.701	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.587 (0.037, 9.209), 0.704	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.007 (-0.044, 0.030), 0.719	
Related AEs Leading to Interruption of Study Drug, n (%)	0	1 (5.3)	4 (6.6)	4 (3.8)	0.955
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.566		0.570 (0.137, 2.367), 0.434	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.587 (0.152, 2.261), 0.438	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		-0.027 (-0.099, 0.045), 0.462	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.7a
Summary of All Adverse Events by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Overall	Placebo (N=6)	Avapritinib 25 mg (N=19)	Placebo (N=61)	Avapritinib 25 mg (N=104)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	0	0	1 (1.6)	1 (1.0)	0.998
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.583 (0.036, 9.484), 0.701	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.587 (0.037, 9.209), 0.704	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.007 (-0.044, 0.030), 0.719	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	1 (1.6)	1 (1.0)	0.998
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.583 (0.036, 9.484), 0.701	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.587 (0.037, 9.209), 0.704	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.007 (-0.044, 0.030), 0.719	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.7a
Summary of All Adverse Events by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Cognitive Effects AESI	Placebo (N=6)	Avapritinib 25 mg (N=19)	Placebo (N=61)	Avapritinib 25 mg (N=104)	P-Value [3]
Any AEs, n (%)	0	1 (5.3)	3 (4.9)	3 (2.9)	0.959
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.566		0.574 (0.112, 2.938), 0.501	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.587 (0.122, 2.816), 0.505	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		-0.020 (-0.083, 0.043), 0.528	
AEs Related to Study Drug, n (%)	0	1 (5.3)	2 (3.3)	2 (1.9)	0.964
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.566		0.578 (0.079, 4.215), 0.585	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.587 (0.085, 4.058), 0.589	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		-0.014 (-0.065, 0.038), 0.609	
Serious AEs, n (%)	0	0	1 (1.6)	0	0.980
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.190	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.016 (-0.048, 0.015), 0.313	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.7a
Summary of All Adverse Events by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Cognitive Effects AESI	Placebo (N=6)	Avapritinib 25 mg (N=19)	Placebo (N=61)	Avapritinib 25 mg (N=104)	P-Value [3]
Grade 1-2 AEs, n (%)	0	1 (5.3)	2 (3.3)	3 (2.9)	0.963
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.566		0.876 (0.142, 5.396), 0.887	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.880 (0.151, 5.119), 0.887	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		-0.004 (-0.059, 0.051), 0.888	
Grade 1-2 AEs Related to Study Drug, n (%)	0	1 (5.3)	2 (3.3)	2 (1.9)	0.964
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.566		0.578 (0.079, 4.215), 0.585	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.587 (0.085, 4.058), 0.589	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		-0.014 (-0.065, 0.038), 0.609	
Grade >=3 AEs, n (%)	0	0	1 (1.6)	0	0.980
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.190	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.016 (-0.048, 0.015), 0.313	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.7a
Summary of All Adverse Events by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Cognitive Effects AESI	Placebo (N=6)	Avapritinib 25 mg (N=19)	Placebo (N=61)	Avapritinib 25 mg (N=104)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	0	1 (5.3)	0	1 (1.0)	0.998
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.566		NE (NE, NE), 0.442	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		0.010 (-0.009, 0.028), 0.315	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	0	0	1 (1.6)	1 (1.0)	0.998
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.583 (0.036, 9.484), 0.701	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.587 (0.037, 9.209), 0.704	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.007 (-0.044, 0.030), 0.719	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Interruption of Study Drug, n (%)	0	1 (5.3)	0	1 (1.0)	0.998
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.566		NE (NE, NE), 0.442	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		0.010 (-0.009, 0.028), 0.315	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.7a
Summary of All Adverse Events by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Cognitive Effects AESI	Placebo (N=6)	Avapritinib 25 mg (N=19)	Placebo (N=61)	Avapritinib 25 mg (N=104)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	0	0	1 (1.6)	1 (1.0)	0.998
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.583 (0.036, 9.484), 0.701	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.587 (0.037, 9.209), 0.704	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.007 (-0.044, 0.030), 0.719	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.7a
Summary of All Adverse Events by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Intracranial Bleeding AESI	Placebo (N=6)	Avapritinib 25 mg (N=19)	Placebo (N=61)	Avapritinib 25 mg (N=104)	P-Value [3]
Any AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Serious AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.7a
Summary of All Adverse Events by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Intracranial Bleeding AESI	Placebo (N=6)	Avapritinib 25 mg (N=19)	Placebo (N=61)	Avapritinib 25 mg (N=104)	P-Value [3]
Grade 1-2 AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade 1-2 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade >=3 AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.7a
Summary of All Adverse Events by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Intracranial Bleeding AESI	Placebo (N=6)	Avapritinib 25 mg (N=19)	Placebo (N=61)	Avapritinib 25 mg (N=104)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Interruption of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.7a
Summary of All Adverse Events by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Intracranial Bleeding AESI	Placebo (N=6)	Avapritinib 25 mg (N=19)	Placebo (N=61)	Avapritinib 25 mg (N=104)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.7a
Summary of All Adverse Events by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Oedema CMQ	Placebo (N=6)	Avapritinib 25 mg (N=19)	Placebo (N=61)	Avapritinib 25 mg (N=104)	P-Value [3]
Any AEs, n (%)	0	5 (26.3)	8 (13.1)	29 (27.9)	0.963
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.160		2.562 (1.086, 6.042), 0.028	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		2.126 (1.039, 4.351), 0.039	
Risk Difference (95% CIs) [2], P-Value		0.263 (0.065, 0.461), 0.009		0.148 (0.027, 0.269), 0.017	
AEs Related to Study Drug, n (%)	0	2 (10.5)	5 (8.2)	22 (21.2)	0.957
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.407		3.005 (1.074, 8.406), 0.030	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		2.581 (1.030, 6.464), 0.043	
Risk Difference (95% CIs) [2], P-Value		0.105 (-0.033, 0.243), 0.135		0.130 (0.025, 0.234), 0.015	
Serious AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.7a
Summary of All Adverse Events by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Oedema CMQ	Placebo (N=6)	Avapritinib 25 mg (N=19)	Placebo (N=61)	Avapritinib 25 mg (N=104)	P-Value [3]
Grade 1-2 AEs, n (%)	0	5 (26.3)	8 (13.1)	29 (27.9)	0.963
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.160		2.562 (1.086, 6.042), 0.028	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		2.126 (1.039, 4.351), 0.039	
Risk Difference (95% CIs) [2], P-Value		0.263 (0.065, 0.461), 0.009		0.148 (0.027, 0.269), 0.017	
Grade 1-2 AEs Related to Study Drug, n (%)	0	2 (10.5)	5 (8.2)	22 (21.2)	0.957
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.407		3.005 (1.074, 8.406), 0.030	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		2.581 (1.030, 6.464), 0.043	
Risk Difference (95% CIs) [2], P-Value		0.105 (-0.033, 0.243), 0.135		0.130 (0.025, 0.234), 0.015	
Grade >=3 AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.7a
Summary of All Adverse Events by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Oedema CMQ	Placebo (N=6)	Avapritinib 25 mg (N=19)	Placebo (N=61)	Avapritinib 25 mg (N=104)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	0	0	0	1 (1.0)	0.981
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.442	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.010 (-0.009, 0.028), 0.315	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	0	0	0	1 (1.0)	0.981
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.442	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.010 (-0.009, 0.028), 0.315	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Interruption of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.7a
Summary of All Adverse Events by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Oedema CMQ	Placebo (N=6)	Avapritinib 25 mg (N=19)	Placebo (N=61)	Avapritinib 25 mg (N=104)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.8a
Summary of All Adverse Events by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Overall	Placebo (N=11)	Avapritinib 25 mg (N=25)	Placebo (N=56)	Avapritinib 25 mg (N=98)	P-Value [3]
Any AEs, n (%)	11 (100.0)	23 (92.0)	51 (91.1)	91 (92.9)	0.951
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.334		1.275 (0.385, 4.222), 0.691	
Relative Risk (95% CIs) [2], P-Value		0.920 (0.820, 1.033), 0.157		1.020 (0.924, 1.125), 0.700	
Risk Difference (95% CIs) [2], P-Value		-0.080 (-0.186, 0.026), 0.140		0.018 (-0.073, 0.108), 0.699	
AEs Related to Study Drug, n (%)	6 (54.5)	15 (60.0)	25 (44.6)	54 (55.1)	0.807
Odds Ratio (95% CIs) [1], P-Value		1.250 (0.299, 5.230), 0.760		1.522 (0.786, 2.945), 0.212	
Relative Risk (95% CIs) [2], P-Value		1.100 (0.587, 2.060), 0.766		1.234 (0.877, 1.738), 0.228	
Risk Difference (95% CIs) [2], P-Value		0.055 (-0.297, 0.406), 0.761		0.105 (-0.059, 0.268), 0.209	
Serious AEs, n (%)	0	3 (12.0)	8 (14.3)	3 (3.1)	0.942
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.230		0.189 (0.048, 0.747), 0.009	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.214 (0.059, 0.775), 0.019	
Risk Difference (95% CIs) [2], P-Value		0.120 (-0.007, 0.247), 0.065		-0.112 (-0.210, -0.014), 0.024	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.8a
Summary of All Adverse Events by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Overall	Placebo (N=11)	Avapritinib 25 mg (N=25)	Placebo (N=56)	Avapritinib 25 mg (N=98)	P-Value [3]
Grade 1-2 AEs, n (%)	11 (100.0)	23 (92.0)	50 (89.3)	91 (92.9)	0.948
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.334		1.560 (0.497, 4.896), 0.443	
Relative Risk (95% CIs) [2], P-Value		0.920 (0.820, 1.033), 0.157		1.040 (0.935, 1.156), 0.469	
Risk Difference (95% CIs) [2], P-Value		-0.080 (-0.186, 0.026), 0.140		0.036 (-0.060, 0.131), 0.465	
Grade 1-2 AEs Related to Study Drug, n (%)	6 (54.5)	15 (60.0)	25 (44.6)	54 (55.1)	0.807
Odds Ratio (95% CIs) [1], P-Value		1.250 (0.299, 5.230), 0.760		1.522 (0.786, 2.945), 0.212	
Relative Risk (95% CIs) [2], P-Value		1.100 (0.587, 2.060), 0.766		1.234 (0.877, 1.738), 0.228	
Risk Difference (95% CIs) [2], P-Value		0.055 (-0.297, 0.406), 0.761		0.105 (-0.059, 0.268), 0.209	
Grade >=3 AEs, n (%)	0	8 (32.0)	14 (25.0)	18 (18.4)	0.943
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.033		0.675 (0.306, 1.490), 0.329	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.735 (0.397, 1.361), 0.327	
Risk Difference (95% CIs) [2], P-Value		0.320 (0.137, 0.503), <0.001		-0.066 (-0.203, 0.071), 0.342	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	2 (3.6)	1 (1.0)	0.994
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.278 (0.025, 3.141), 0.271	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.286 (0.026, 3.081), 0.302	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.026 (-0.078, 0.027), 0.341	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.8a
Summary of All Adverse Events by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Overall	Placebo (N=11)	Avapritinib 25 mg (N=25)	Placebo (N=56)	Avapritinib 25 mg (N=98)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	0	3 (12.0)	9 (16.1)	8 (8.2)	0.938
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.230		0.464 (0.168, 1.282), 0.132	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.508 (0.208, 1.242), 0.138	
Risk Difference (95% CIs) [2], P-Value		0.120 (-0.007, 0.247), 0.065		-0.079 (-0.189, 0.031), 0.160	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	0	0	1 (1.8)	2 (2.0)	>0.999
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		1.146 (0.102, 12.928), 0.912	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		1.143 (0.106, 12.323), 0.912	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.003 (-0.042, 0.047), 0.911	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	1 (1.8)	1 (1.0)	0.998
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.567 (0.035, 9.245), 0.687	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.571 (0.036, 8.959), 0.690	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.008 (-0.048, 0.032), 0.708	
Related AEs Leading to Interruption of Study Drug, n (%)	0	2 (8.0)	4 (7.1)	3 (3.1)	0.956
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.334		0.411 (0.088, 1.905), 0.242	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.429 (0.099, 1.846), 0.256	
Risk Difference (95% CIs) [2], P-Value		0.080 (-0.026, 0.186), 0.140		-0.041 (-0.116, 0.035), 0.290	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.8a
Summary of All Adverse Events by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Overall	Placebo (N=11)	Avapritinib 25 mg (N=25)	Placebo (N=56)	Avapritinib 25 mg (N=98)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	0	0	1 (1.8)	1 (1.0)	0.998
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.567 (0.035, 9.245), 0.687	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.571 (0.036, 8.959), 0.690	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.008 (-0.048, 0.032), 0.708	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	1 (1.8)	1 (1.0)	0.998
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.567 (0.035, 9.245), 0.687	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.571 (0.036, 8.959), 0.690	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.008 (-0.048, 0.032), 0.708	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.8a
Summary of All Adverse Events by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Cognitive Effects AESI	Placebo (N=11)	Avapritinib 25 mg (N=25)	Placebo (N=56)	Avapritinib 25 mg (N=98)	P-Value [3]
Any AEs, n (%)	0	1 (4.0)	3 (5.4)	3 (3.1)	0.946
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.501		0.558 (0.109, 2.862), 0.479	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.571 (0.119, 2.736), 0.484	
Risk Difference (95% CIs) [2], P-Value		0.040 (-0.037, 0.117), 0.307		-0.023 (-0.091, 0.045), 0.509	
AEs Related to Study Drug, n (%)	0	1 (4.0)	2 (3.6)	2 (2.0)	0.952
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.501		0.563 (0.077, 4.107), 0.566	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.571 (0.083, 3.946), 0.570	
Risk Difference (95% CIs) [2], P-Value		0.040 (-0.037, 0.117), 0.307		-0.015 (-0.071, 0.041), 0.593	
Serious AEs, n (%)	0	0	1 (1.8)	0	0.973
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.184	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.018 (-0.053, 0.017), 0.313	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.8a
Summary of All Adverse Events by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Cognitive Effects AESI	Placebo (N=11)	Avapritinib 25 mg (N=25)	Placebo (N=56)	Avapritinib 25 mg (N=98)	P-Value [3]
Grade 1-2 AEs, n (%)	0	1 (4.0)	2 (3.6)	3 (3.1)	0.951
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.501		0.853 (0.138, 5.263), 0.864	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.857 (0.148, 4.976), 0.864	
Risk Difference (95% CIs) [2], P-Value		0.040 (-0.037, 0.117), 0.307		-0.005 (-0.064, 0.054), 0.866	
Grade 1-2 AEs Related to Study Drug, n (%)	0	1 (4.0)	2 (3.6)	2 (2.0)	0.952
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.501		0.563 (0.077, 4.107), 0.566	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.571 (0.083, 3.946), 0.570	
Risk Difference (95% CIs) [2], P-Value		0.040 (-0.037, 0.117), 0.307		-0.015 (-0.071, 0.041), 0.593	
Grade >=3 AEs, n (%)	0	0	1 (1.8)	0	0.973
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.184	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.018 (-0.053, 0.017), 0.313	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.8a
Summary of All Adverse Events by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Cognitive Effects AESI	Placebo (N=11)	Avapritinib 25 mg (N=25)	Placebo (N=56)	Avapritinib 25 mg (N=98)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	0	1 (4.0)	0	1 (1.0)	0.998
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.501		NE (NE, NE), 0.448	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.040 (-0.037, 0.117), 0.307		0.010 (-0.010, 0.030), 0.315	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	0	0	1 (1.8)	1 (1.0)	0.998
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.567 (0.035, 9.245), 0.687	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.571 (0.036, 8.959), 0.690	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.008 (-0.048, 0.032), 0.708	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Interruption of Study Drug, n (%)	0	1 (4.0)	0	1 (1.0)	0.998
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.501		NE (NE, NE), 0.448	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.040 (-0.037, 0.117), 0.307		0.010 (-0.010, 0.030), 0.315	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.8a
Summary of All Adverse Events by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Cognitive Effects AESI	Placebo (N=11)	Avapritinib 25 mg (N=25)	Placebo (N=56)	Avapritinib 25 mg (N=98)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	0	0	1 (1.8)	1 (1.0)	0.998
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.567 (0.035, 9.245), 0.687	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.571 (0.036, 8.959), 0.690	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.008 (-0.048, 0.032), 0.708	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.8a
Summary of All Adverse Events by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Intracranial Bleeding AESI	Placebo (N=11)	Avapritinib 25 mg (N=25)	Placebo (N=56)	Avapritinib 25 mg (N=98)	P-Value [3]
Any AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Serious AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.8a
Summary of All Adverse Events by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Intracranial Bleeding AESI	Placebo (N=11)	Avapritinib 25 mg (N=25)	Placebo (N=56)	Avapritinib 25 mg (N=98)	P-Value [3]
Grade 1-2 AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade 1-2 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade >=3 AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.8a
Summary of All Adverse Events by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Intracranial Bleeding AESI	Placebo (N=11)	Avapritinib 25 mg (N=25)	Placebo (N=56)	Avapritinib 25 mg (N=98)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Interruption of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.8a
Summary of All Adverse Events by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Intracranial Bleeding AESI	Placebo (N=11)	Avapritinib 25 mg (N=25)	Placebo (N=56)	Avapritinib 25 mg (N=98)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.8a
Summary of All Adverse Events by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Oedema CMQ	Placebo (N=11)	Avapritinib 25 mg (N=25)	Placebo (N=56)	Avapritinib 25 mg (N=98)	P-Value [3]
Any AEs, n (%)	2 (18.2)	6 (24.0)	6 (10.7)	28 (28.6)	0.409
Odds Ratio (95% CIs) [1], P-Value		1.421 (0.238, 8.478), 0.699		3.333 (1.285, 8.649), 0.010	
Relative Risk (95% CIs) [2], P-Value		1.320 (0.314, 5.541), 0.704		2.667 (1.176, 6.044), 0.019	
Risk Difference (95% CIs) [2], P-Value		0.058 (-0.225, 0.341), 0.687		0.179 (0.058, 0.299), 0.004	
AEs Related to Study Drug, n (%)	2 (18.2)	3 (12.0)	3 (5.4)	21 (21.4)	0.082
Odds Ratio (95% CIs) [1], P-Value		0.614 (0.087, 4.313), 0.621		4.818 (1.368, 16.974), 0.008	
Relative Risk (95% CIs) [2], P-Value		0.660 (0.128, 3.411), 0.620		4.000 (1.249, 12.815), 0.020	
Risk Difference (95% CIs) [2], P-Value		-0.062 (-0.323, 0.199), 0.643		0.161 (0.060, 0.261), 0.002	
Serious AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.8a
Summary of All Adverse Events by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Oedema CMQ	Placebo (N=11)	Avapritinib 25 mg (N=25)	Placebo (N=56)	Avapritinib 25 mg (N=98)	P-Value [3]
Grade 1-2 AEs, n (%)	2 (18.2)	6 (24.0)	6 (10.7)	28 (28.6)	0.409
Odds Ratio (95% CIs) [1], P-Value		1.421 (0.238, 8.478), 0.699		3.333 (1.285, 8.649), 0.010	
Relative Risk (95% CIs) [2], P-Value		1.320 (0.314, 5.541), 0.704		2.667 (1.176, 6.044), 0.019	
Risk Difference (95% CIs) [2], P-Value		0.058 (-0.225, 0.341), 0.687		0.179 (0.058, 0.299), 0.004	
Grade 1-2 AEs Related to Study Drug, n (%)	2 (18.2)	3 (12.0)	3 (5.4)	21 (21.4)	0.082
Odds Ratio (95% CIs) [1], P-Value		0.614 (0.087, 4.313), 0.621		4.818 (1.368, 16.974), 0.008	
Relative Risk (95% CIs) [2], P-Value		0.660 (0.128, 3.411), 0.620		4.000 (1.249, 12.815), 0.020	
Risk Difference (95% CIs) [2], P-Value		-0.062 (-0.323, 0.199), 0.643		0.161 (0.060, 0.261), 0.002	
Grade >=3 AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.8a
Summary of All Adverse Events by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Oedema CMQ	Placebo (N=11)	Avapritinib 25 mg (N=25)	Placebo (N=56)	Avapritinib 25 mg (N=98)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	0	0	0	1 (1.0)	0.976
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.448	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.010 (-0.010, 0.030), 0.315	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	0	0	0	1 (1.0)	0.976
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.448	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.010 (-0.010, 0.030), 0.315	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Interruption of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.1.2.8a
Summary of All Adverse Events by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Oedema CMQ	Placebo (N=11)	Avapritinib 25 mg (N=25)	Placebo (N=56)	Avapritinib 25 mg (N=98)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.2.1.2.1a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	<65 Years Placebo (N=56)	<65 Years Avapritinib 25 mg (N=117)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=6)	P-Value [3]
Gastrointestinal disorders, n (%)	11 (19.6)	26 (22.2)	3 (27.3)	1 (16.7)	0.561
Odds Ratio (95% CIs) [1], P-Value		1.169 (0.530, 2.576), 0.699		0.533 (0.043, 6.655), 0.622	
Relative Risk (95% CIs) [2], P-Value		1.131 (0.603, 2.122), 0.701		0.611 (0.080, 4.666), 0.635	
Risk Difference (95% CIs) [2], P-Value		0.026 (-0.103, 0.154), 0.694		-0.106 (-0.504, 0.292), 0.601	
Nausea, n (%)	7 (12.5)	17 (14.5)	3 (27.3)	1 (16.7)	0.559
Odds Ratio (95% CIs) [1], P-Value		1.190 (0.463, 3.059), 0.718		0.533 (0.043, 6.655), 0.622	
Relative Risk (95% CIs) [2], P-Value		1.162 (0.512, 2.641), 0.719		0.611 (0.080, 4.666), 0.635	
Risk Difference (95% CIs) [2], P-Value		0.020 (-0.087, 0.128), 0.712		-0.106 (-0.504, 0.292), 0.601	
Diarrhoea, n (%)	5 (8.9)	15 (12.8)	2 (18.2)	0	0.952
Odds Ratio (95% CIs) [1], P-Value		1.500 (0.516, 4.358), 0.454		NE (NE, NE), 0.266	
Relative Risk (95% CIs) [2], P-Value		1.436 (0.549, 3.753), 0.460		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.039 (-0.057, 0.135), 0.428		-0.182 (-0.410, 0.046), 0.118	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.2.1a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	<65 Years Placebo (N=56)	<65 Years Avapritinib 25 mg (N=117)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=6)	P-Value [3]
Infections and infestations, n (%)	7 (12.5)	16 (13.7)	1 (9.1)	1 (16.7)	0.711
Odds Ratio (95% CIs) [1], P-Value		1.109 (0.428, 2.872), 0.831		2.000 (0.102, 39.079), 0.643	
Relative Risk (95% CIs) [2], P-Value		1.094 (0.477, 2.507), 0.832		1.833 (0.138, 24.369), 0.646	
Risk Difference (95% CIs) [2], P-Value		0.012 (-0.095, 0.118), 0.829		0.076 (-0.267, 0.419), 0.665	
COVID-19, n (%)	7 (12.5)	16 (13.7)	1 (9.1)	1 (16.7)	0.711
Odds Ratio (95% CIs) [1], P-Value		1.109 (0.428, 2.872), 0.831		2.000 (0.102, 39.079), 0.643	
Relative Risk (95% CIs) [2], P-Value		1.094 (0.477, 2.507), 0.832		1.833 (0.138, 24.369), 0.646	
Risk Difference (95% CIs) [2], P-Value		0.012 (-0.095, 0.118), 0.829		0.076 (-0.267, 0.419), 0.665	
Nervous system disorders, n (%)	13 (23.2)	32 (27.4)	4 (36.4)	1 (16.7)	0.335
Odds Ratio (95% CIs) [1], P-Value		1.245 (0.593, 2.614), 0.562		0.350 (0.029, 4.153), 0.394	
Relative Risk (95% CIs) [2], P-Value		1.178 (0.673, 2.064), 0.566		0.458 (0.065, 3.230), 0.434	
Risk Difference (95% CIs) [2], P-Value		0.041 (-0.096, 0.178), 0.554		-0.197 (-0.609, 0.215), 0.349	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.2.1a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	<65 Years Placebo (N=56)	<65 Years Avapritinib 25 mg (N=117)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=6)	P-Value [3]
Nervous system disorders (cont.)					
Headache, n (%)	11 (19.6)	23 (19.7)	3 (27.3)	1 (16.7)	0.641
Odds Ratio (95% CIs) [1], P-Value		1.001 (0.449, 2.231), 0.998		0.533 (0.043, 6.655), 0.622	
Relative Risk (95% CIs) [2], P-Value		1.001 (0.526, 1.906), 0.998		0.611 (0.080, 4.666), 0.635	
Risk Difference (95% CIs) [2], P-Value		0.000 (-0.126, 0.127), 0.998		-0.106 (-0.504, 0.292), 0.601	
Dizziness, n (%)	5 (8.9)	14 (12.0)	1 (9.1)	0	0.957
Odds Ratio (95% CIs) [1], P-Value		1.386 (0.473, 4.062), 0.550		NE (NE, NE), 0.446	
Relative Risk (95% CIs) [2], P-Value		1.340 (0.508, 3.536), 0.554		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.030 (-0.065, 0.125), 0.531		-0.091 (-0.261, 0.079), 0.294	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.2.2a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Male Placebo (N=15)	Male Avapritinib 25 mg (N=35)	Female Placebo (N=52)	Female Avapritinib 25 mg (N=88)	P-Value [3]
Gastrointestinal disorders, n (%)	2 (13.3)	9 (25.7)	12 (23.1)	18 (20.5)	0.310
Odds Ratio (95% CIs) [1], P-Value		2.250 (0.423, 11.959), 0.333		0.857 (0.375, 1.960), 0.715	
Relative Risk (95% CIs) [2], P-Value		1.929 (0.472, 7.881), 0.360		0.886 (0.465, 1.689), 0.714	
Risk Difference (95% CIs) [2], P-Value		0.124 (-0.101, 0.349), 0.280		-0.026 (-0.168, 0.116), 0.718	
Nausea, n (%)	2 (13.3)	7 (20.0)	8 (15.4)	11 (12.5)	0.469
Odds Ratio (95% CIs) [1], P-Value		1.625 (0.296, 8.927), 0.574		0.786 (0.294, 2.100), 0.630	
Relative Risk (95% CIs) [2], P-Value		1.500 (0.352, 6.397), 0.584		0.813 (0.349, 1.889), 0.630	
Risk Difference (95% CIs) [2], P-Value		0.067 (-0.150, 0.284), 0.547		-0.029 (-0.149, 0.091), 0.637	
Diarrhoea, n (%)	0	3 (8.6)	7 (13.5)	12 (13.6)	0.955
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.242		1.015 (0.373, 2.766), 0.977	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.013 (0.426, 2.410), 0.977	
Risk Difference (95% CIs) [2], P-Value		0.086 (-0.007, 0.178), 0.070		0.002 (-0.115, 0.119), 0.977	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.2.2a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Male Placebo (N=15)	Male Avapritinib 25 mg (N=35)	Female Placebo (N=52)	Female Avapritinib 25 mg (N=88)	P-Value [3]
Infections and infestations, n (%)	4 (26.7)	5 (14.3)	4 (7.7)	12 (13.6)	0.144
Odds Ratio (95% CIs) [1], P-Value		0.458 (0.104, 2.024), 0.296		1.895 (0.578, 6.215), 0.285	
Relative Risk (95% CIs) [2], P-Value		0.536 (0.167, 1.722), 0.295		1.773 (0.603, 5.212), 0.298	
Risk Difference (95% CIs) [2], P-Value		-0.124 (-0.376, 0.128), 0.336		0.059 (-0.042, 0.161), 0.253	
COVID-19, n (%)	4 (26.7)	5 (14.3)	4 (7.7)	12 (13.6)	0.144
Odds Ratio (95% CIs) [1], P-Value		0.458 (0.104, 2.024), 0.296		1.895 (0.578, 6.215), 0.285	
Relative Risk (95% CIs) [2], P-Value		0.536 (0.167, 1.722), 0.295		1.773 (0.603, 5.212), 0.298	
Risk Difference (95% CIs) [2], P-Value		-0.124 (-0.376, 0.128), 0.336		0.059 (-0.042, 0.161), 0.253	
Nervous system disorders, n (%)	0	8 (22.9)	17 (32.7)	25 (28.4)	0.955
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.043		0.817 (0.389, 1.716), 0.593	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.869 (0.521, 1.450), 0.591	
Risk Difference (95% CIs) [2], P-Value		0.229 (0.089, 0.368), 0.001		-0.043 (-0.201, 0.116), 0.596	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.2.2a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Male Placebo (N=15)	Male Avapritinib 25 mg (N=35)	Female Placebo (N=52)	Female Avapritinib 25 mg (N=88)	P-Value [3]
Nervous system disorders (cont.)					
Headache, n (%)	0	7 (20.0)	14 (26.9)	17 (19.3)	0.938
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.062		0.650 (0.289, 1.460), 0.295	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.718 (0.386, 1.332), 0.293	
Risk Difference (95% CIs) [2], P-Value		0.200 (0.067, 0.333), 0.003		-0.076 (-0.222, 0.070), 0.308	
Dizziness, n (%)	0	4 (11.4)	6 (11.5)	10 (11.4)	0.955
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.172		0.983 (0.335, 2.882), 0.975	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.985 (0.380, 2.552), 0.975	
Risk Difference (95% CIs) [2], P-Value		0.114 (0.009, 0.220), 0.034		-0.002 (-0.111, 0.108), 0.975	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.2.3a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	North America Placebo (N=32)	North America Avapritinib 25 mg (N=52)	Europe Placebo (N=35)	Europe Avapritinib 25 mg (N=71)	P-Value [3]
Gastrointestinal disorders, n (%)	7 (21.9)	9 (17.3)	7 (20.0)	18 (25.4)	0.429
Odds Ratio (95% CIs) [1], P-Value		0.748 (0.248, 2.254), 0.605		1.358 (0.507, 3.641), 0.542	
Relative Risk (95% CIs) [2], P-Value		0.791 (0.327, 1.915), 0.604		1.268 (0.585, 2.747), 0.548	
Risk Difference (95% CIs) [2], P-Value		-0.046 (-0.222, 0.131), 0.612		0.054 (-0.113, 0.220), 0.529	
Nausea, n (%)	5 (15.6)	7 (13.5)	5 (14.3)	11 (15.5)	0.754
Odds Ratio (95% CIs) [1], P-Value		0.840 (0.242, 2.911), 0.783		1.100 (0.350, 3.455), 0.870	
Relative Risk (95% CIs) [2], P-Value		0.862 (0.299, 2.486), 0.783		1.085 (0.408, 2.880), 0.871	
Risk Difference (95% CIs) [2], P-Value		-0.022 (-0.178, 0.135), 0.786		0.012 (-0.131, 0.155), 0.869	
Diarrhoea, n (%)	4 (12.5)	5 (9.6)	3 (8.6)	10 (14.1)	0.390
Odds Ratio (95% CIs) [1], P-Value		0.745 (0.184, 3.006), 0.678		1.749 (0.449, 6.808), 0.416	
Relative Risk (95% CIs) [2], P-Value		0.769 (0.223, 2.655), 0.678		1.643 (0.483, 5.594), 0.427	
Risk Difference (95% CIs) [2], P-Value		-0.029 (-0.169, 0.111), 0.686		0.055 (-0.068, 0.178), 0.380	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.2.3a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	North America Placebo (N=32)	North America Avapritinib 25 mg (N=52)	Europe Placebo (N=35)	Europe Avapritinib 25 mg (N=71)	P-Value [3]
Infections and infestations, n (%)	3 (9.4)	4 (7.7)	5 (14.3)	13 (18.3)	0.602
Odds Ratio (95% CIs) [1], P-Value		0.806 (0.168, 3.858), 0.786		1.345 (0.438, 4.128), 0.604	
Relative Risk (95% CIs) [2], P-Value		0.821 (0.196, 3.431), 0.786		1.282 (0.496, 3.310), 0.608	
Risk Difference (95% CIs) [2], P-Value		-0.017 (-0.141, 0.107), 0.791		0.040 (-0.106, 0.187), 0.591	
COVID-19, n (%)	3 (9.4)	4 (7.7)	5 (14.3)	13 (18.3)	0.602
Odds Ratio (95% CIs) [1], P-Value		0.806 (0.168, 3.858), 0.786		1.345 (0.438, 4.128), 0.604	
Relative Risk (95% CIs) [2], P-Value		0.821 (0.196, 3.431), 0.786		1.282 (0.496, 3.310), 0.608	
Risk Difference (95% CIs) [2], P-Value		-0.017 (-0.141, 0.107), 0.791		0.040 (-0.106, 0.187), 0.591	
Nervous system disorders, n (%)	7 (21.9)	15 (28.8)	10 (28.6)	18 (25.4)	0.446
Odds Ratio (95% CIs) [1], P-Value		1.448 (0.517, 4.058), 0.480		0.849 (0.343, 2.104), 0.724	
Relative Risk (95% CIs) [2], P-Value		1.319 (0.604, 2.881), 0.488		0.887 (0.459, 1.714), 0.722	
Risk Difference (95% CIs) [2], P-Value		0.070 (-0.119, 0.259), 0.469		-0.032 (-0.213, 0.148), 0.727	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.2.3a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	North America Placebo (N=32)	North America Avapritinib 25 mg (N=52)	Europe Placebo (N=35)	Europe Avapritinib 25 mg (N=71)	P-Value [3]
Nervous system disorders (cont.)					
Headache, n (%)	7 (21.9)	11 (21.2)	7 (20.0)	13 (18.3)	0.930
Odds Ratio (95% CIs) [1], P-Value		0.958 (0.329, 2.794), 0.938		0.897 (0.322, 2.495), 0.834	
Relative Risk (95% CIs) [2], P-Value		0.967 (0.418, 2.238), 0.938		0.915 (0.401, 2.089), 0.834	
Risk Difference (95% CIs) [2], P-Value		-0.007 (-0.188, 0.174), 0.938		-0.017 (-0.177, 0.143), 0.836	
Dizziness, n (%)	1 (3.1)	6 (11.5)	5 (14.3)	8 (11.3)	0.186
Odds Ratio (95% CIs) [1], P-Value		4.043 (0.464, 35.253), 0.175		0.762 (0.230, 2.527), 0.656	
Relative Risk (95% CIs) [2], P-Value		3.692 (0.466, 29.281), 0.216		0.789 (0.278, 2.235), 0.655	
Risk Difference (95% CIs) [2], P-Value		0.084 (-0.022, 0.190), 0.119		-0.030 (-0.167, 0.107), 0.667	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.2.9a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=27)	United States Avapritinib 25 mg (N=44)	Germany Placebo (N=14)	Germany Avapritinib 25 mg (N=17)
Gastrointestinal disorders, n (%)	5 (18.5)	7 (15.9)	3 (21.4)	4 (23.5)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Nausea, n (%)	4 (14.8)	5 (11.4)	3 (21.4)	3 (17.6)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Diarrhoea, n (%)	2 (7.4)	4 (9.1)	0	1 (5.9)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Infections and infestations, n (%)	2 (7.4)	3 (6.8)	1 (7.1)	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.2.9a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Spain		France	
	Placebo (N=3)	Avapritinib 25 mg (N=13)	Placebo (N=5)	Avapritinib 25 mg (N=10)
Gastrointestinal disorders, n (%)	0	2 (15.4)	1 (20.0)	2 (20.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Nausea, n (%)	0	1 (7.7)	1 (20.0)	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Diarrhoea, n (%)	0	2 (15.4)	0	2 (20.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Infections and infestations, n (%)	0	3 (23.1)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.2.9a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=10)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Gastrointestinal disorders, n (%)	1 (20.0)	3 (30.0)	2 (40.0)	2 (25.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Nausea, n (%)	0	2 (20.0)	1 (20.0)	2 (25.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Diarrhoea, n (%)	1 (20.0)	2 (20.0)	2 (40.0)	1 (12.5)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Infections and infestations, n (%)	2 (40.0)	2 (20.0)	1 (20.0)	1 (12.5)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.2.9a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=7)	Norway Placebo (N=2)	Norway Avapritinib 25 mg (N=5)
Gastrointestinal disorders, n (%)	0	3 (42.9)	1 (50.0)	2 (40.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Nausea, n (%)	0	1 (14.3)	1 (50.0)	2 (40.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Diarrhoea, n (%)	0	2 (28.6)	1 (50.0)	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Infections and infestations, n (%)	0	2 (28.6)	1 (50.0)	3 (60.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.2.9a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=2)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=3)
Gastrointestinal disorders, n (%)	0	1 (50.0)	0	1 (33.3)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Nausea, n (%)	0	1 (50.0)	0	1 (33.3)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Diarrhoea, n (%)	0	0	0	1 (33.3)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Infections and infestations, n (%)	0	1 (50.0)	0	1 (33.3)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.2.9a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Switzerland		Sweden	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=1)	Avapritinib 25 mg (N=1)
Gastrointestinal disorders, n (%)	1 (100.0)	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Nausea, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Diarrhoea, n (%)	1 (100.0)	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Infections and infestations, n (%)	0	0	1 (100.0)	1 (100.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.2.9a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Gastrointestinal disorders, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Nausea, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Diarrhoea, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Infections and infestations, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.2.9a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=27)	United States Avapritinib 25 mg (N=44)	Germany Placebo (N=14)	Germany Avapritinib 25 mg (N=17)
Infections and infestations (cont.)	2 (7.4)	3 (6.8)	1 (7.1)	0
COVID-19, n (%)	2 (7.4)	3 (6.8)	1 (7.1)	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Nervous system disorders, n (%)	4 (14.8)	13 (29.5)	5 (35.7)	5 (29.4)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Headache, n (%)	4 (14.8)	9 (20.5)	3 (21.4)	3 (17.6)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dizziness, n (%)	1 (3.7)	6 (13.6)	3 (21.4)	3 (17.6)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.2.9a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=13)	France Placebo (N=5)	France Avapritinib 25 mg (N=10)
Infections and infestations (cont.)	0	3 (23.1)	0	0
COVID-19, n (%)	0	3 (23.1)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Nervous system disorders, n (%)	0	4 (30.8)	1 (20.0)	1 (10.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Headache, n (%)	0	3 (23.1)	1 (20.0)	1 (10.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dizziness, n (%)	0	1 (7.7)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.2.9a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=10)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Infections and infestations (cont.)	2 (40.0)	2 (20.0)	1 (20.0)	1 (12.5)
COVID-19, n (%)	2 (40.0)	2 (20.0)	1 (20.0)	1 (12.5)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Nervous system disorders, n (%)	2 (40.0)	1 (10.0)	3 (60.0)	2 (25.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Headache, n (%)	1 (20.0)	1 (10.0)	3 (60.0)	2 (25.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dizziness, n (%)	2 (40.0)	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.2.9a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=7)	Norway Placebo (N=2)	Norway Avapritinib 25 mg (N=5)
Infections and infestations (cont.)	0	2 (28.6)	1 (50.0)	3 (60.0)
COVID-19, n (%)	0	2 (28.6)	1 (50.0)	3 (60.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Nervous system disorders, n (%)	0	2 (28.6)	1 (50.0)	2 (40.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Headache, n (%)	0	1 (14.3)	1 (50.0)	2 (40.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dizziness, n (%)	0	2 (28.6)	0	1 (20.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.2.9a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=2)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=3)
Infections and infestations (cont.)	0	1 (50.0)	0	1 (33.3)
COVID-19, n (%)	0	1 (50.0)	0	1 (33.3)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Nervous system disorders, n (%)	0	2 (100.0)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Headache, n (%)	0	2 (100.0)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dizziness, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.2.9a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Switzerland		Sweden	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=1)	Avapritinib 25 mg (N=1)
Infections and infestations (cont.)	0	0	1 (100.0)	1 (100.0)
COVID-19, n (%)	0	0	1 (100.0)	1 (100.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Nervous system disorders, n (%)	1 (100.0)	1 (50.0)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Headache, n (%)	1 (100.0)	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dizziness, n (%)	0	1 (50.0)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.2.9a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Infections and infestations (cont.)	0	0	-
COVID-19, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Nervous system disorders, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Headache, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Dizziness, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.2.4a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Moderate Placebo (N=22)	Moderate Avapritinib 25 mg (N=37)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=86)	P-Value [3]
Gastrointestinal disorders, n (%)	5 (22.7)	9 (24.3)	9 (20.0)	18 (20.9)	0.968
Odds Ratio (95% CIs) [1], P-Value		1.093 (0.314, 3.808), 0.889		1.059 (0.432, 2.595), 0.901	
Relative Risk (95% CIs) [2], P-Value		1.070 (0.411, 2.788), 0.889		1.047 (0.512, 2.138), 0.901	
Risk Difference (95% CIs) [2], P-Value		0.016 (-0.207, 0.239), 0.888		0.009 (-0.136, 0.154), 0.900	
Nausea, n (%)	4 (18.2)	5 (13.5)	6 (13.3)	13 (15.1)	0.582
Odds Ratio (95% CIs) [1], P-Value		0.703 (0.167, 2.956), 0.630		1.158 (0.408, 3.283), 0.783	
Relative Risk (95% CIs) [2], P-Value		0.743 (0.223, 2.478), 0.629		1.134 (0.462, 2.782), 0.784	
Risk Difference (95% CIs) [2], P-Value		-0.047 (-0.242, 0.149), 0.639		0.018 (-0.107, 0.143), 0.780	
Diarrhoea, n (%)	3 (13.6)	5 (13.5)	4 (8.9)	10 (11.6)	0.758
Odds Ratio (95% CIs) [1], P-Value		0.990 (0.212, 4.615), 0.989		1.349 (0.398, 4.569), 0.630	
Relative Risk (95% CIs) [2], P-Value		0.991 (0.262, 3.749), 0.989		1.308 (0.435, 3.938), 0.633	
Risk Difference (95% CIs) [2], P-Value		-0.001 (-0.182, 0.180), 0.989		0.027 (-0.080, 0.135), 0.617	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.2.4a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Moderate Placebo (N=22)	Moderate Avapritinib 25 mg (N=37)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=86)	P-Value [3]
Infections and infestations, n (%)	1 (4.5)	3 (8.1)	7 (15.6)	14 (16.3)	0.663
Odds Ratio (95% CIs) [1], P-Value		1.853 (0.181, 18.999), 0.599		1.056 (0.393, 2.837), 0.915	
Relative Risk (95% CIs) [2], P-Value		1.784 (0.197, 16.112), 0.606		1.047 (0.455, 2.406), 0.915	
Risk Difference (95% CIs) [2], P-Value		0.036 (-0.088, 0.159), 0.573		0.007 (-0.124, 0.139), 0.914	
COVID-19, n (%)	1 (4.5)	3 (8.1)	7 (15.6)	14 (16.3)	0.663
Odds Ratio (95% CIs) [1], P-Value		1.853 (0.181, 18.999), 0.599		1.056 (0.393, 2.837), 0.915	
Relative Risk (95% CIs) [2], P-Value		1.784 (0.197, 16.112), 0.606		1.047 (0.455, 2.406), 0.915	
Risk Difference (95% CIs) [2], P-Value		0.036 (-0.088, 0.159), 0.573		0.007 (-0.124, 0.139), 0.914	
Nervous system disorders, n (%)	6 (27.3)	7 (18.9)	11 (24.4)	26 (30.2)	0.314
Odds Ratio (95% CIs) [1], P-Value		0.622 (0.179, 2.167), 0.454		1.339 (0.589, 3.044), 0.485	
Relative Risk (95% CIs) [2], P-Value		0.694 (0.267, 1.801), 0.453		1.237 (0.675, 2.267), 0.492	
Risk Difference (95% CIs) [2], P-Value		-0.084 (-0.308, 0.141), 0.467		0.058 (-0.101, 0.217), 0.475	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.2.4a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Moderate Placebo (N=22)	Moderate Avapritinib 25 mg (N=37)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=86)	P-Value [3]
Nervous system disorders (cont.)					
Headache, n (%)	5 (22.7)	5 (13.5)	9 (20.0)	19 (22.1)	0.363
Odds Ratio (95% CIs) [1], P-Value		0.531 (0.135, 2.095), 0.362		1.134 (0.466, 2.764), 0.781	
Relative Risk (95% CIs) [2], P-Value		0.595 (0.194, 1.825), 0.364		1.105 (0.545, 2.239), 0.782	
Risk Difference (95% CIs) [2], P-Value		-0.092 (-0.299, 0.115), 0.383		0.021 (-0.125, 0.167), 0.779	
Dizziness, n (%)	1 (4.5)	4 (10.8)	5 (11.1)	10 (11.6)	0.494
Odds Ratio (95% CIs) [1], P-Value		2.545 (0.266, 24.359), 0.403		1.053 (0.337, 3.290), 0.930	
Relative Risk (95% CIs) [2], P-Value		2.378 (0.284, 19.950), 0.425		1.047 (0.381, 2.877), 0.930	
Risk Difference (95% CIs) [2], P-Value		0.063 (-0.070, 0.195), 0.354		0.005 (-0.109, 0.119), 0.929	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.2.5a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	<20 ng/mL Placebo (N=13)	<20 ng/mL Avapritinib 25 mg (N=26)	>=20 ng/mL Placebo (N=54)	>=20 ng/mL Avapritinib 25 mg (N=97)	P-Value [3]
Gastrointestinal disorders, n (%)	3 (23.1)	8 (30.8)	11 (20.4)	19 (19.6)	0.620
Odds Ratio (95% CIs) [1], P-Value		1.481 (0.319, 6.881), 0.615		0.952 (0.415, 2.185), 0.908	
Relative Risk (95% CIs) [2], P-Value		1.333 (0.423, 4.202), 0.623		0.962 (0.495, 1.868), 0.908	
Risk Difference (95% CIs) [2], P-Value		0.077 (-0.213, 0.367), 0.603		-0.008 (-0.141, 0.126), 0.908	
Nausea, n (%)	2 (15.4)	7 (26.9)	8 (14.8)	11 (11.3)	0.319
Odds Ratio (95% CIs) [1], P-Value		2.026 (0.356, 11.522), 0.420		0.735 (0.276, 1.957), 0.537	
Relative Risk (95% CIs) [2], P-Value		1.750 (0.422, 7.265), 0.441		0.765 (0.328, 1.787), 0.537	
Risk Difference (95% CIs) [2], P-Value		0.115 (-0.144, 0.375), 0.384		-0.035 (-0.149, 0.079), 0.550	
Diarrhoea, n (%)	1 (7.7)	4 (15.4)	6 (11.1)	11 (11.3)	0.558
Odds Ratio (95% CIs) [1], P-Value		2.182 (0.218, 21.793), 0.498		1.023 (0.356, 2.940), 0.966	
Relative Risk (95% CIs) [2], P-Value		2.000 (0.248, 16.133), 0.515		1.021 (0.400, 2.606), 0.966	
Risk Difference (95% CIs) [2], P-Value		0.077 (-0.124, 0.277), 0.452		0.002 (-0.103, 0.107), 0.966	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.2.5a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	<20 ng/mL Placebo (N=13)	<20 ng/mL Avapritinib 25 mg (N=26)	>=20 ng/mL Placebo (N=54)	>=20 ng/mL Avapritinib 25 mg (N=97)	P-Value [3]
Infections and infestations, n (%)	1 (7.7)	4 (15.4)	7 (13.0)	13 (13.4)	0.561
Odds Ratio (95% CIs) [1], P-Value		2.182 (0.218, 21.793), 0.498		1.039 (0.388, 2.785), 0.939	
Relative Risk (95% CIs) [2], P-Value		2.000 (0.248, 16.133), 0.515		1.034 (0.439, 2.435), 0.939	
Risk Difference (95% CIs) [2], P-Value		0.077 (-0.124, 0.277), 0.452		0.004 (-0.108, 0.117), 0.939	
COVID-19, n (%)	1 (7.7)	4 (15.4)	7 (13.0)	13 (13.4)	0.561
Odds Ratio (95% CIs) [1], P-Value		2.182 (0.218, 21.793), 0.498		1.039 (0.388, 2.785), 0.939	
Relative Risk (95% CIs) [2], P-Value		2.000 (0.248, 16.133), 0.515		1.034 (0.439, 2.435), 0.939	
Risk Difference (95% CIs) [2], P-Value		0.077 (-0.124, 0.277), 0.452		0.004 (-0.108, 0.117), 0.939	
Nervous system disorders, n (%)	3 (23.1)	8 (30.8)	14 (25.9)	25 (25.8)	0.646
Odds Ratio (95% CIs) [1], P-Value		1.481 (0.319, 6.881), 0.615		0.992 (0.464, 2.121), 0.984	
Relative Risk (95% CIs) [2], P-Value		1.333 (0.423, 4.202), 0.623		0.994 (0.566, 1.746), 0.984	
Risk Difference (95% CIs) [2], P-Value		0.077 (-0.213, 0.367), 0.603		-0.002 (-0.147, 0.144), 0.984	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.2.5a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	<20 ng/mL Placebo (N=13)	<20 ng/mL Avapritinib 25 mg (N=26)	>=20 ng/mL Placebo (N=54)	>=20 ng/mL Avapritinib 25 mg (N=97)	P-Value [3]
Nervous system disorders (cont.)					
Headache, n (%)	3 (23.1)	6 (23.1)	11 (20.4)	18 (18.6)	0.899
Odds Ratio (95% CIs) [1], P-Value		1.000 (0.206, 4.856), >0.999		0.891 (0.386, 2.057), 0.786	
Relative Risk (95% CIs) [2], P-Value		1.000 (0.297, 3.372), >0.999		0.911 (0.465, 1.784), 0.786	
Risk Difference (95% CIs) [2], P-Value		0.000 (-0.281, 0.281), >0.999		-0.018 (-0.151, 0.114), 0.788	
Dizziness, n (%)	1 (7.7)	4 (15.4)	5 (9.3)	10 (10.3)	0.613
Odds Ratio (95% CIs) [1], P-Value		2.182 (0.218, 21.793), 0.498		1.126 (0.364, 3.484), 0.836	
Relative Risk (95% CIs) [2], P-Value		2.000 (0.248, 16.133), 0.515		1.113 (0.401, 3.090), 0.837	
Risk Difference (95% CIs) [2], P-Value		0.077 (-0.124, 0.277), 0.452		0.011 (-0.088, 0.109), 0.834	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.2.6a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Number of Baseline BSC <4 Placebo (N=32)	 Avapritinib 25 mg (N=63)	Number of Baseline BSC >=4 Placebo (N=35)	 Avapritinib 25 mg (N=60)	P-Value [3]
Gastrointestinal disorders, n (%)	7 (21.9)	15 (23.8)	7 (20.0)	12 (20.0)	0.883
Odds Ratio (95% CIs) [1], P-Value		1.116 (0.403, 3.092), 0.833		1.000 (0.353, 2.835), >0.999	
Relative Risk (95% CIs) [2], P-Value		1.088 (0.494, 2.398), 0.833		1.000 (0.434, 2.302), >0.999	
Risk Difference (95% CIs) [2], P-Value		0.019 (-0.158, 0.197), 0.831		0.000 (-0.167, 0.167), >0.999	
Nausea, n (%)	6 (18.8)	9 (14.3)	4 (11.4)	9 (15.0)	0.460
Odds Ratio (95% CIs) [1], P-Value		0.722 (0.232, 2.245), 0.573		1.368 (0.388, 4.819), 0.625	
Relative Risk (95% CIs) [2], P-Value		0.762 (0.297, 1.953), 0.571		1.313 (0.436, 3.949), 0.628	
Risk Difference (95% CIs) [2], P-Value		-0.045 (-0.205, 0.116), 0.586		0.036 (-0.103, 0.175), 0.614	
Diarrhoea, n (%)	2 (6.3)	7 (11.1)	5 (14.3)	8 (13.3)	0.494
Odds Ratio (95% CIs) [1], P-Value		1.875 (0.366, 9.597), 0.444		0.923 (0.277, 3.078), 0.896	
Relative Risk (95% CIs) [2], P-Value		1.778 (0.392, 8.070), 0.456		0.933 (0.331, 2.632), 0.896	
Risk Difference (95% CIs) [2], P-Value		0.049 (-0.066, 0.163), 0.404		-0.010 (-0.154, 0.135), 0.897	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.2.6a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Number of Baseline BSC <4 Placebo (N=32)	 Avapritinib 25 mg (N=63)	Number of Baseline BSC >=4 Placebo (N=35)	 Avapritinib 25 mg (N=60)	P-Value [3]
Infections and infestations, n (%)	2 (6.3)	8 (12.7)	6 (17.1)	9 (15.0)	0.350
Odds Ratio (95% CIs) [1], P-Value		2.182 (0.435, 10.938), 0.333		0.853 (0.276, 2.638), 0.782	
Relative Risk (95% CIs) [2], P-Value		2.032 (0.458, 9.014), 0.351		0.875 (0.340, 2.252), 0.782	
Risk Difference (95% CIs) [2], P-Value		0.064 (-0.053, 0.182), 0.282		-0.021 (-0.176, 0.133), 0.785	
COVID-19, n (%)	2 (6.3)	8 (12.7)	6 (17.1)	9 (15.0)	0.350
Odds Ratio (95% CIs) [1], P-Value		2.182 (0.435, 10.938), 0.333		0.853 (0.276, 2.638), 0.782	
Relative Risk (95% CIs) [2], P-Value		2.032 (0.458, 9.014), 0.351		0.875 (0.340, 2.252), 0.782	
Risk Difference (95% CIs) [2], P-Value		0.064 (-0.053, 0.182), 0.282		-0.021 (-0.176, 0.133), 0.785	
Nervous system disorders, n (%)	11 (34.4)	16 (25.4)	6 (17.1)	17 (28.3)	0.129
Odds Ratio (95% CIs) [1], P-Value		0.650 (0.258, 1.638), 0.359		1.911 (0.673, 5.423), 0.219	
Relative Risk (95% CIs) [2], P-Value		0.739 (0.390, 1.400), 0.353		1.653 (0.719, 3.798), 0.237	
Risk Difference (95% CIs) [2], P-Value		-0.090 (-0.286, 0.107), 0.371		0.112 (-0.057, 0.281), 0.195	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.2.6a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Number of Baseline BSC <4 Placebo (N=32)	Number of Baseline BSC <4 Avapritinib 25 mg (N=63)	Number of Baseline BSC >=4 Placebo (N=35)	Number of Baseline BSC >=4 Avapritinib 25 mg (N=60)	P-Value [3]
Nervous system disorders (cont.)					
Headache, n (%)	9 (28.1)	13 (20.6)	5 (14.3)	11 (18.3)	0.360
Odds Ratio (95% CIs) [1], P-Value		0.664 (0.249, 1.776), 0.413		1.347 (0.426, 4.257), 0.611	
Relative Risk (95% CIs) [2], P-Value		0.734 (0.352, 1.531), 0.409		1.283 (0.486, 3.390), 0.615	
Risk Difference (95% CIs) [2], P-Value		-0.075 (-0.260, 0.110), 0.428		0.040 (-0.111, 0.192), 0.601	
Dizziness, n (%)	4 (12.5)	5 (7.9)	2 (5.7)	9 (15.0)	0.145
Odds Ratio (95% CIs) [1], P-Value		0.603 (0.150, 2.423), 0.473		2.912 (0.592, 14.329), 0.172	
Relative Risk (95% CIs) [2], P-Value		0.635 (0.183, 2.203), 0.474		2.625 (0.601, 11.467), 0.200	
Risk Difference (95% CIs) [2], P-Value		-0.046 (-0.178, 0.087), 0.500		0.093 (-0.026, 0.212), 0.125	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.2.7a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Yes Placebo (N=6)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=61)	No Avapritinib 25 mg (N=104)	P-Value [3]
Gastrointestinal disorders, n (%)	1 (16.7)	2 (10.5)	13 (21.3)	25 (24.0)	0.619
Odds Ratio (95% CIs) [1], P-Value		0.588 (0.044, 7.914), 0.687		1.168 (0.546, 2.499), 0.688	
Relative Risk (95% CIs) [2], P-Value		0.632 (0.069, 5.804), 0.685		1.128 (0.625, 2.037), 0.690	
Risk Difference (95% CIs) [2], P-Value		-0.061 (-0.390, 0.267), 0.714		0.027 (-0.104, 0.159), 0.685	
Nausea, n (%)	0	1 (5.3)	10 (16.4)	17 (16.3)	0.956
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.566		0.997 (0.424, 2.341), 0.994	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.997 (0.488, 2.037), 0.994	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		-0.000 (-0.117, 0.116), 0.994	
Diarrhoea, n (%)	1 (16.7)	2 (10.5)	6 (9.8)	13 (12.5)	0.574
Odds Ratio (95% CIs) [1], P-Value		0.588 (0.044, 7.914), 0.687		1.310 (0.471, 3.645), 0.605	
Relative Risk (95% CIs) [2], P-Value		0.632 (0.069, 5.804), 0.685		1.271 (0.509, 3.171), 0.607	
Risk Difference (95% CIs) [2], P-Value		-0.061 (-0.390, 0.267), 0.714		0.027 (-0.071, 0.125), 0.595	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.2.7a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Yes Placebo (N=6)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=61)	No Avapritinib 25 mg (N=104)	P-Value [3]
Infections and infestations, n (%)	1 (16.7)	1 (5.3)	7 (11.5)	16 (15.4)	0.305
Odds Ratio (95% CIs) [1], P-Value		0.278 (0.015, 5.273), 0.369		1.403 (0.542, 3.629), 0.484	
Relative Risk (95% CIs) [2], P-Value		0.316 (0.023, 4.318), 0.388		1.341 (0.585, 3.075), 0.489	
Risk Difference (95% CIs) [2], P-Value		-0.114 (-0.429, 0.201), 0.477		0.039 (-0.067, 0.145), 0.469	
COVID-19, n (%)	1 (16.7)	1 (5.3)	7 (11.5)	16 (15.4)	0.305
Odds Ratio (95% CIs) [1], P-Value		0.278 (0.015, 5.273), 0.369		1.403 (0.542, 3.629), 0.484	
Relative Risk (95% CIs) [2], P-Value		0.316 (0.023, 4.318), 0.388		1.341 (0.585, 3.075), 0.489	
Risk Difference (95% CIs) [2], P-Value		-0.114 (-0.429, 0.201), 0.477		0.039 (-0.067, 0.145), 0.469	
Nervous system disorders, n (%)	1 (16.7)	2 (10.5)	16 (26.2)	31 (29.8)	0.607
Odds Ratio (95% CIs) [1], P-Value		0.588 (0.044, 7.914), 0.687		1.194 (0.588, 2.426), 0.623	
Relative Risk (95% CIs) [2], P-Value		0.632 (0.069, 5.804), 0.685		1.136 (0.680, 1.900), 0.626	
Risk Difference (95% CIs) [2], P-Value		-0.061 (-0.390, 0.267), 0.714		0.036 (-0.105, 0.177), 0.619	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.2.7a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Yes Placebo (N=6)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=61)	No Avapritinib 25 mg (N=104)	P-Value [3]
Nervous system disorders (cont.)					
Headache, n (%)	1 (16.7)	1 (5.3)	13 (21.3)	23 (22.1)	0.392
Odds Ratio (95% CIs) [1], P-Value		0.278 (0.015, 5.273), 0.369		1.048 (0.486, 2.260), 0.904	
Relative Risk (95% CIs) [2], P-Value		0.316 (0.023, 4.318), 0.388		1.038 (0.568, 1.895), 0.904	
Risk Difference (95% CIs) [2], P-Value		-0.114 (-0.429, 0.201), 0.477		0.008 (-0.122, 0.138), 0.904	
Dizziness, n (%)	0	1 (5.3)	6 (9.8)	13 (12.5)	0.962
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.566		1.310 (0.471, 3.645), 0.605	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.271 (0.509, 3.171), 0.607	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		0.027 (-0.071, 0.125), 0.595	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.2.8a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=25)	No Placebo (N=56)	No Avapritinib 25 mg (N=98)	P-Value [3]
Gastrointestinal disorders, n (%)	1 (9.1)	6 (24.0)	13 (23.2)	21 (21.4)	0.303
Odds Ratio (95% CIs) [1], P-Value		3.158 (0.332, 29.998), 0.298		0.902 (0.411, 1.980), 0.797	
Relative Risk (95% CIs) [2], P-Value		2.640 (0.359, 19.404), 0.340		0.923 (0.502, 1.697), 0.797	
Risk Difference (95% CIs) [2], P-Value		0.149 (-0.089, 0.388), 0.221		-0.018 (-0.155, 0.119), 0.799	
Nausea, n (%)	1 (9.1)	5 (20.0)	9 (16.1)	13 (13.3)	0.363
Odds Ratio (95% CIs) [1], P-Value		2.500 (0.256, 24.375), 0.418		0.799 (0.318, 2.007), 0.632	
Relative Risk (95% CIs) [2], P-Value		2.200 (0.290, 16.693), 0.446		0.825 (0.377, 1.808), 0.631	
Risk Difference (95% CIs) [2], P-Value		0.109 (-0.122, 0.340), 0.355		-0.028 (-0.145, 0.089), 0.639	
Diarrhoea, n (%)	0	4 (16.0)	7 (12.5)	11 (11.2)	0.959
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.159		0.885 (0.322, 2.431), 0.813	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.898 (0.369, 2.184), 0.812	
Risk Difference (95% CIs) [2], P-Value		0.160 (0.016, 0.304), 0.029		-0.013 (-0.120, 0.094), 0.815	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.2.8a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=25)	No Placebo (N=56)	No Avapritinib 25 mg (N=98)	P-Value [3]
Infections and infestations, n (%)	1 (9.1)	5 (20.0)	7 (12.5)	12 (12.2)	0.459
Odds Ratio (95% CIs) [1], P-Value		2.500 (0.256, 24.375), 0.418		0.977 (0.361, 2.644), 0.963	
Relative Risk (95% CIs) [2], P-Value		2.200 (0.290, 16.693), 0.446		0.980 (0.409, 2.344), 0.963	
Risk Difference (95% CIs) [2], P-Value		0.109 (-0.122, 0.340), 0.355		-0.003 (-0.111, 0.106), 0.963	
COVID-19, n (%)	1 (9.1)	5 (20.0)	7 (12.5)	12 (12.2)	0.459
Odds Ratio (95% CIs) [1], P-Value		2.500 (0.256, 24.375), 0.418		0.977 (0.361, 2.644), 0.963	
Relative Risk (95% CIs) [2], P-Value		2.200 (0.290, 16.693), 0.446		0.980 (0.409, 2.344), 0.963	
Risk Difference (95% CIs) [2], P-Value		0.109 (-0.122, 0.340), 0.355		-0.003 (-0.111, 0.106), 0.963	
Nervous system disorders, n (%)	1 (9.1)	5 (20.0)	16 (28.6)	28 (28.6)	0.453
Odds Ratio (95% CIs) [1], P-Value		2.500 (0.256, 24.375), 0.418		1.000 (0.483, 2.068), >0.999	
Relative Risk (95% CIs) [2], P-Value		2.200 (0.290, 16.693), 0.446		1.000 (0.595, 1.681), >0.999	
Risk Difference (95% CIs) [2], P-Value		0.109 (-0.122, 0.340), 0.355		0.000 (-0.148, 0.148), >0.999	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.2.8a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=25)	No Placebo (N=56)	No Avapritinib 25 mg (N=98)	P-Value [3]
Nervous system disorders (cont.)					
Headache, n (%)	0	3 (12.0)	14 (25.0)	21 (21.4)	0.951
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.230		0.818 (0.377, 1.774), 0.611	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.857 (0.475, 1.548), 0.609	
Risk Difference (95% CIs) [2], P-Value		0.120 (-0.007, 0.247), 0.065		-0.036 (-0.175, 0.104), 0.616	
Dizziness, n (%)	1 (9.1)	2 (8.0)	5 (8.9)	12 (12.2)	0.725
Odds Ratio (95% CIs) [1], P-Value		0.870 (0.070, 10.728), 0.913		1.423 (0.474, 4.273), 0.528	
Relative Risk (95% CIs) [2], P-Value		0.880 (0.089, 8.719), 0.913		1.371 (0.509, 3.692), 0.532	
Risk Difference (95% CIs) [2], P-Value		-0.011 (-0.211, 0.190), 0.915		0.033 (-0.066, 0.132), 0.511	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.1a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	<65 Years Placebo (N=56)	<65 Years Avapritinib 25 mg (N=117)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=6)	P-Value [3]
Gastrointestinal disorders, n (%)	11 (19.6)	26 (22.2)	3 (27.3)	1 (16.7)	0.561
Odds Ratio (95% CIs) [1], P-Value		1.169 (0.530, 2.576), 0.699		0.533 (0.043, 6.655), 0.622	
Relative Risk (95% CIs) [2], P-Value		1.131 (0.603, 2.122), 0.701		0.611 (0.080, 4.666), 0.635	
Risk Difference (95% CIs) [2], P-Value		0.026 (-0.103, 0.154), 0.694		-0.106 (-0.504, 0.292), 0.601	
Nausea, n (%)	7 (12.5)	17 (14.5)	3 (27.3)	1 (16.7)	0.559
Odds Ratio (95% CIs) [1], P-Value		1.190 (0.463, 3.059), 0.718		0.533 (0.043, 6.655), 0.622	
Relative Risk (95% CIs) [2], P-Value		1.162 (0.512, 2.641), 0.719		0.611 (0.080, 4.666), 0.635	
Risk Difference (95% CIs) [2], P-Value		0.020 (-0.087, 0.128), 0.712		-0.106 (-0.504, 0.292), 0.601	
Diarrhoea, n (%)	5 (8.9)	15 (12.8)	2 (18.2)	0	0.952
Odds Ratio (95% CIs) [1], P-Value		1.500 (0.516, 4.358), 0.454		NE (NE, NE), 0.266	
Relative Risk (95% CIs) [2], P-Value		1.436 (0.549, 3.753), 0.460		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.039 (-0.057, 0.135), 0.428		-0.182 (-0.410, 0.046), 0.118	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.1a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	<65 Years Placebo (N=56)	<65 Years Avapritinib 25 mg (N=117)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=6)	P-Value [3]
General disorders and administration site conditions, n (%)	7 (12.5)	20 (17.1)	1 (9.1)	1 (16.7)	0.837
Odds Ratio (95% CIs) [1], P-Value		1.443 (0.571, 3.646), 0.436		2.000 (0.102, 39.079), 0.643	
Relative Risk (95% CIs) [2], P-Value		1.368 (0.615, 3.042), 0.443		1.833 (0.138, 24.369), 0.646	
Risk Difference (95% CIs) [2], P-Value		0.046 (-0.064, 0.156), 0.414		0.076 (-0.267, 0.419), 0.665	
Fatigue, n (%)	4 (7.1)	12 (10.3)	1 (9.1)	0	0.960
Odds Ratio (95% CIs) [1], P-Value		1.486 (0.457, 4.832), 0.508		NE (NE, NE), 0.446	
Relative Risk (95% CIs) [2], P-Value		1.436 (0.485, 4.253), 0.514		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.031 (-0.056, 0.118), 0.483		-0.091 (-0.261, 0.079), 0.294	
Oedema peripheral, n (%)	3 (5.4)	10 (8.5)	0	1 (16.7)	0.950
Odds Ratio (95% CIs) [1], P-Value		1.651 (0.436, 6.253), 0.456		NE (NE, NE), 0.163	
Relative Risk (95% CIs) [2], P-Value		1.595 (0.457, 5.570), 0.464		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.032 (-0.046, 0.110), 0.421		0.167 (-0.132, 0.465), 0.273	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.1a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	<65 Years Placebo (N=56)	<65 Years Avapritinib 25 mg (N=117)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=6)	P-Value [3]
Infections and infestations, n (%)	7 (12.5)	16 (13.7)	1 (9.1)	1 (16.7)	0.711
Odds Ratio (95% CIs) [1], P-Value		1.109 (0.428, 2.872), 0.831		2.000 (0.102, 39.079), 0.643	
Relative Risk (95% CIs) [2], P-Value		1.094 (0.477, 2.507), 0.832		1.833 (0.138, 24.369), 0.646	
Risk Difference (95% CIs) [2], P-Value		0.012 (-0.095, 0.118), 0.829		0.076 (-0.267, 0.419), 0.665	
COVID-19, n (%)	7 (12.5)	16 (13.7)	1 (9.1)	1 (16.7)	0.711
Odds Ratio (95% CIs) [1], P-Value		1.109 (0.428, 2.872), 0.831		2.000 (0.102, 39.079), 0.643	
Relative Risk (95% CIs) [2], P-Value		1.094 (0.477, 2.507), 0.832		1.833 (0.138, 24.369), 0.646	
Risk Difference (95% CIs) [2], P-Value		0.012 (-0.095, 0.118), 0.829		0.076 (-0.267, 0.419), 0.665	
Musculoskeletal and connective tissue disorders, n (%)	4 (7.1)	10 (8.5)	1 (9.1)	1 (16.7)	0.761
Odds Ratio (95% CIs) [1], P-Value		1.215 (0.364, 4.058), 0.751		2.000 (0.102, 39.079), 0.643	
Relative Risk (95% CIs) [2], P-Value		1.197 (0.392, 3.649), 0.752		1.833 (0.138, 24.369), 0.646	
Risk Difference (95% CIs) [2], P-Value		0.014 (-0.070, 0.098), 0.744		0.076 (-0.267, 0.419), 0.665	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.1a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	<65 Years Placebo (N=56)	<65 Years Avapritinib 25 mg (N=117)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=6)	P-Value [3]
Musculoskeletal and connective tissue disorders (cont.)					
Arthralgia, n (%)	4 (7.1)	10 (8.5)	1 (9.1)	1 (16.7)	0.761
Odds Ratio (95% CIs) [1], P-Value		1.215 (0.364, 4.058), 0.751		2.000 (0.102, 39.079), 0.643	
Relative Risk (95% CIs) [2], P-Value		1.197 (0.392, 3.649), 0.752		1.833 (0.138, 24.369), 0.646	
Risk Difference (95% CIs) [2], P-Value		0.014 (-0.070, 0.098), 0.744		0.076 (-0.267, 0.419), 0.665	
Nervous system disorders, n (%)	13 (23.2)	32 (27.4)	4 (36.4)	1 (16.7)	0.335
Odds Ratio (95% CIs) [1], P-Value		1.245 (0.593, 2.614), 0.562		0.350 (0.029, 4.153), 0.394	
Relative Risk (95% CIs) [2], P-Value		1.178 (0.673, 2.064), 0.566		0.458 (0.065, 3.230), 0.434	
Risk Difference (95% CIs) [2], P-Value		0.041 (-0.096, 0.178), 0.554		-0.197 (-0.609, 0.215), 0.349	
Headache, n (%)	11 (19.6)	23 (19.7)	3 (27.3)	1 (16.7)	0.641
Odds Ratio (95% CIs) [1], P-Value		1.001 (0.449, 2.231), 0.998		0.533 (0.043, 6.655), 0.622	
Relative Risk (95% CIs) [2], P-Value		1.001 (0.526, 1.906), 0.998		0.611 (0.080, 4.666), 0.635	
Risk Difference (95% CIs) [2], P-Value		0.000 (-0.126, 0.127), 0.998		-0.106 (-0.504, 0.292), 0.601	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.1a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	<65 Years Placebo (N=56)	<65 Years Avapritinib 25 mg (N=117)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=6)	P-Value [3]
Nervous system disorders (cont.)					
Dizziness, n (%)	5 (8.9)	14 (12.0)	1 (9.1)	0	0.957
Odds Ratio (95% CIs) [1], P-Value		1.386 (0.473, 4.062), 0.550		NE (NE, NE), 0.446	
Relative Risk (95% CIs) [2], P-Value		1.340 (0.508, 3.536), 0.554		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.030 (-0.065, 0.125), 0.531		-0.091 (-0.261, 0.079), 0.294	
Skin and subcutaneous tissue disorders, n (%)	4 (7.1)	10 (8.5)	1 (9.1)	0	0.962
Odds Ratio (95% CIs) [1], P-Value		1.215 (0.364, 4.058), 0.751		NE (NE, NE), 0.446	
Relative Risk (95% CIs) [2], P-Value		1.197 (0.392, 3.649), 0.752		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.014 (-0.070, 0.098), 0.744		-0.091 (-0.261, 0.079), 0.294	
Pruritus, n (%)	4 (7.1)	10 (8.5)	1 (9.1)	0	0.962
Odds Ratio (95% CIs) [1], P-Value		1.215 (0.364, 4.058), 0.751		NE (NE, NE), 0.446	
Relative Risk (95% CIs) [2], P-Value		1.197 (0.392, 3.649), 0.752		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.014 (-0.070, 0.098), 0.744		-0.091 (-0.261, 0.079), 0.294	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.1a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	<65 Years Placebo (N=56)	<65 Years Avapritinib 25 mg (N=117)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=6)	P-Value [3]
Vascular disorders, n (%)	2 (3.6)	11 (9.4)	0	0	0.995
Odds Ratio (95% CIs) [1], P-Value		2.802 (0.600, 13.094), 0.174		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		2.632 (0.604, 11.479), 0.198		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.058 (-0.014, 0.130), 0.112		NA (NA, NA), NA	
Flushing, n (%)	2 (3.6)	11 (9.4)	0	0	0.995
Odds Ratio (95% CIs) [1], P-Value		2.802 (0.600, 13.094), 0.174		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		2.632 (0.604, 11.479), 0.198		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.058 (-0.014, 0.130), 0.112		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.2a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Male Placebo (N=15)	Male Avapritinib 25 mg (N=35)	Female Placebo (N=52)	Female Avapritinib 25 mg (N=88)	P-Value [3]
Gastrointestinal disorders, n (%)	2 (13.3)	9 (25.7)	12 (23.1)	18 (20.5)	0.310
Odds Ratio (95% CIs) [1], P-Value		2.250 (0.423, 11.959), 0.333		0.857 (0.375, 1.960), 0.715	
Relative Risk (95% CIs) [2], P-Value		1.929 (0.472, 7.881), 0.360		0.886 (0.465, 1.689), 0.714	
Risk Difference (95% CIs) [2], P-Value		0.124 (-0.101, 0.349), 0.280		-0.026 (-0.168, 0.116), 0.718	
Nausea, n (%)	2 (13.3)	7 (20.0)	8 (15.4)	11 (12.5)	0.469
Odds Ratio (95% CIs) [1], P-Value		1.625 (0.296, 8.927), 0.574		0.786 (0.294, 2.100), 0.630	
Relative Risk (95% CIs) [2], P-Value		1.500 (0.352, 6.397), 0.584		0.813 (0.349, 1.889), 0.630	
Risk Difference (95% CIs) [2], P-Value		0.067 (-0.150, 0.284), 0.547		-0.029 (-0.149, 0.091), 0.637	
Diarrhoea, n (%)	0	3 (8.6)	7 (13.5)	12 (13.6)	0.955
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.242		1.015 (0.373, 2.766), 0.977	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.013 (0.426, 2.410), 0.977	
Risk Difference (95% CIs) [2], P-Value		0.086 (-0.007, 0.178), 0.070		0.002 (-0.115, 0.119), 0.977	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.2a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Male Placebo (N=15)	Male Avapritinib 25 mg (N=35)	Female Placebo (N=52)	Female Avapritinib 25 mg (N=88)	P-Value [3]
General disorders and administration site conditions, n (%)	4 (26.7)	5 (14.3)	4 (7.7)	16 (18.2)	0.067
Odds Ratio (95% CIs) [1], P-Value		0.458 (0.104, 2.024), 0.296		2.667 (0.840, 8.463), 0.087	
Relative Risk (95% CIs) [2], P-Value		0.536 (0.167, 1.722), 0.295		2.364 (0.835, 6.692), 0.105	
Risk Difference (95% CIs) [2], P-Value		-0.124 (-0.376, 0.128), 0.336		0.105 (-0.003, 0.213), 0.058	
Fatigue, n (%)	3 (20.0)	3 (8.6)	2 (3.8)	9 (10.2)	0.089
Odds Ratio (95% CIs) [1], P-Value		0.375 (0.066, 2.120), 0.254		2.848 (0.591, 13.725), 0.175	
Relative Risk (95% CIs) [2], P-Value		0.429 (0.097, 1.886), 0.262		2.659 (0.597, 11.838), 0.199	
Risk Difference (95% CIs) [2], P-Value		-0.114 (-0.337, 0.108), 0.314		0.064 (-0.018, 0.146), 0.128	
Oedema peripheral, n (%)	1 (6.7)	3 (8.6)	2 (3.8)	8 (9.1)	0.656
Odds Ratio (95% CIs) [1], P-Value		1.313 (0.125, 13.744), 0.820		2.500 (0.510, 12.250), 0.244	
Relative Risk (95% CIs) [2], P-Value		1.286 (0.145, 11.383), 0.821		2.364 (0.522, 10.711), 0.265	
Risk Difference (95% CIs) [2], P-Value		0.019 (-0.138, 0.176), 0.812		0.052 (-0.027, 0.132), 0.197	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.2a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Male Placebo (N=15)	Male Avapritinib 25 mg (N=35)	Female Placebo (N=52)	Female Avapritinib 25 mg (N=88)	P-Value [3]
Infections and infestations, n (%)	4 (26.7)	5 (14.3)	4 (7.7)	12 (13.6)	0.144
Odds Ratio (95% CIs) [1], P-Value		0.458 (0.104, 2.024), 0.296		1.895 (0.578, 6.215), 0.285	
Relative Risk (95% CIs) [2], P-Value		0.536 (0.167, 1.722), 0.295		1.773 (0.603, 5.212), 0.298	
Risk Difference (95% CIs) [2], P-Value		-0.124 (-0.376, 0.128), 0.336		0.059 (-0.042, 0.161), 0.253	
COVID-19, n (%)	4 (26.7)	5 (14.3)	4 (7.7)	12 (13.6)	0.144
Odds Ratio (95% CIs) [1], P-Value		0.458 (0.104, 2.024), 0.296		1.895 (0.578, 6.215), 0.285	
Relative Risk (95% CIs) [2], P-Value		0.536 (0.167, 1.722), 0.295		1.773 (0.603, 5.212), 0.298	
Risk Difference (95% CIs) [2], P-Value		-0.124 (-0.376, 0.128), 0.336		0.059 (-0.042, 0.161), 0.253	
Musculoskeletal and connective tissue disorders, n (%)	1 (6.7)	2 (5.7)	4 (7.7)	9 (10.2)	0.736
Odds Ratio (95% CIs) [1], P-Value		0.848 (0.071, 10.137), 0.897		1.367 (0.399, 4.683), 0.618	
Relative Risk (95% CIs) [2], P-Value		0.857 (0.084, 8.748), 0.897		1.330 (0.431, 4.103), 0.620	
Risk Difference (95% CIs) [2], P-Value		-0.010 (-0.157, 0.138), 0.900		0.025 (-0.071, 0.122), 0.606	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.2a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Male Placebo (N=15)	Male Avapritinib 25 mg (N=35)	Female Placebo (N=52)	Female Avapritinib 25 mg (N=88)	P-Value [3]
Musculoskeletal and connective tissue disorders (cont.)					
Arthralgia, n (%)	1 (6.7)	2 (5.7)	4 (7.7)	9 (10.2)	0.736
Odds Ratio (95% CIs) [1], P-Value		0.848 (0.071, 10.137), 0.897		1.367 (0.399, 4.683), 0.618	
Relative Risk (95% CIs) [2], P-Value		0.857 (0.084, 8.748), 0.897		1.330 (0.431, 4.103), 0.620	
Risk Difference (95% CIs) [2], P-Value		-0.010 (-0.157, 0.138), 0.900		0.025 (-0.071, 0.122), 0.606	
Nervous system disorders, n (%)	0	8 (22.9)	17 (32.7)	25 (28.4)	0.955
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.043		0.817 (0.389, 1.716), 0.593	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.869 (0.521, 1.450), 0.591	
Risk Difference (95% CIs) [2], P-Value		0.229 (0.089, 0.368), 0.001		-0.043 (-0.201, 0.116), 0.596	
Headache, n (%)	0	7 (20.0)	14 (26.9)	17 (19.3)	0.938
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.062		0.650 (0.289, 1.460), 0.295	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.718 (0.386, 1.332), 0.293	
Risk Difference (95% CIs) [2], P-Value		0.200 (0.067, 0.333), 0.003		-0.076 (-0.222, 0.070), 0.308	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.2a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Male Placebo (N=15)	Male Avapritinib 25 mg (N=35)	Female Placebo (N=52)	Female Avapritinib 25 mg (N=88)	P-Value [3]
Nervous system disorders (cont.)					
Dizziness, n (%)	0	4 (11.4)	6 (11.5)	10 (11.4)	0.955
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.172		0.983 (0.335, 2.882), 0.975	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.985 (0.380, 2.552), 0.975	
Risk Difference (95% CIs) [2], P-Value		0.114 (0.009, 0.220), 0.034		-0.002 (-0.111, 0.108), 0.975	
Skin and subcutaneous tissue disorders, n (%)	0	3 (8.6)	5 (9.6)	7 (8.0)	0.960
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.242		0.812 (0.244, 2.704), 0.734	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.827 (0.277, 2.473), 0.734	
Risk Difference (95% CIs) [2], P-Value		0.086 (-0.007, 0.178), 0.070		-0.017 (-0.115, 0.081), 0.740	
Pruritus, n (%)	0	3 (8.6)	5 (9.6)	7 (8.0)	0.960
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.242		0.812 (0.244, 2.704), 0.734	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.827 (0.277, 2.473), 0.734	
Risk Difference (95% CIs) [2], P-Value		0.086 (-0.007, 0.178), 0.070		-0.017 (-0.115, 0.081), 0.740	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.2a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Male Placebo (N=15)	Male Avapritinib 25 mg (N=35)	Female Placebo (N=52)	Female Avapritinib 25 mg (N=88)	P-Value [3]
Vascular disorders, n (%)	0	3 (8.6)	2 (3.8)	8 (9.1)	0.950
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.242		2.500 (0.510, 12.250), 0.244	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		2.364 (0.522, 10.711), 0.265	
Risk Difference (95% CIs) [2], P-Value		0.086 (-0.007, 0.178), 0.070		0.052 (-0.027, 0.132), 0.197	
Flushing, n (%)	0	3 (8.6)	2 (3.8)	8 (9.1)	0.950
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.242		2.500 (0.510, 12.250), 0.244	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		2.364 (0.522, 10.711), 0.265	
Risk Difference (95% CIs) [2], P-Value		0.086 (-0.007, 0.178), 0.070		0.052 (-0.027, 0.132), 0.197	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.3a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	North America Placebo (N=32)	North America Avapritinib 25 mg (N=52)	Europe Placebo (N=35)	Europe Avapritinib 25 mg (N=71)	P-Value [3]
Gastrointestinal disorders, n (%)	7 (21.9)	9 (17.3)	7 (20.0)	18 (25.4)	0.429
Odds Ratio (95% CIs) [1], P-Value		0.748 (0.248, 2.254), 0.605		1.358 (0.507, 3.641), 0.542	
Relative Risk (95% CIs) [2], P-Value		0.791 (0.327, 1.915), 0.604		1.268 (0.585, 2.747), 0.548	
Risk Difference (95% CIs) [2], P-Value		-0.046 (-0.222, 0.131), 0.612		0.054 (-0.113, 0.220), 0.529	
Nausea, n (%)	5 (15.6)	7 (13.5)	5 (14.3)	11 (15.5)	0.754
Odds Ratio (95% CIs) [1], P-Value		0.840 (0.242, 2.911), 0.783		1.100 (0.350, 3.455), 0.870	
Relative Risk (95% CIs) [2], P-Value		0.862 (0.299, 2.486), 0.783		1.085 (0.408, 2.880), 0.871	
Risk Difference (95% CIs) [2], P-Value		-0.022 (-0.178, 0.135), 0.786		0.012 (-0.131, 0.155), 0.869	
Diarrhoea, n (%)	4 (12.5)	5 (9.6)	3 (8.6)	10 (14.1)	0.390
Odds Ratio (95% CIs) [1], P-Value		0.745 (0.184, 3.006), 0.678		1.749 (0.449, 6.808), 0.416	
Relative Risk (95% CIs) [2], P-Value		0.769 (0.223, 2.655), 0.678		1.643 (0.483, 5.594), 0.427	
Risk Difference (95% CIs) [2], P-Value		-0.029 (-0.169, 0.111), 0.686		0.055 (-0.068, 0.178), 0.380	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.3a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	North America Placebo (N=32)	North America Avapritinib 25 mg (N=52)	Europe Placebo (N=35)	Europe Avapritinib 25 mg (N=71)	P-Value [3]
General disorders and administration site conditions, n (%)	3 (9.4)	10 (19.2)	5 (14.3)	11 (15.5)	0.418
Odds Ratio (95% CIs) [1], P-Value		2.302 (0.582, 9.096), 0.225		1.100 (0.350, 3.455), 0.870	
Relative Risk (95% CIs) [2], P-Value		2.051 (0.610, 6.898), 0.246		1.085 (0.408, 2.880), 0.871	
Risk Difference (95% CIs) [2], P-Value		0.099 (-0.049, 0.246), 0.189		0.012 (-0.131, 0.155), 0.869	
Fatigue, n (%)	1 (3.1)	7 (13.5)	4 (11.4)	5 (7.0)	0.106
Odds Ratio (95% CIs) [1], P-Value		4.822 (0.565, 41.177), 0.117		0.587 (0.147, 2.339), 0.446	
Relative Risk (95% CIs) [2], P-Value		4.308 (0.555, 33.411), 0.162		0.616 (0.176, 2.153), 0.448	
Risk Difference (95% CIs) [2], P-Value		0.103 (-0.007, 0.214), 0.067		-0.044 (-0.165, 0.077), 0.478	
Oedema peripheral, n (%)	2 (6.3)	5 (9.6)	1 (2.9)	6 (8.5)	0.630
Odds Ratio (95% CIs) [1], P-Value		1.596 (0.291, 8.758), 0.588		3.138 (0.363, 27.140), 0.275	
Relative Risk (95% CIs) [2], P-Value		1.538 (0.317, 7.466), 0.593		2.958 (0.370, 23.627), 0.306	
Risk Difference (95% CIs) [2], P-Value		0.034 (-0.082, 0.150), 0.570		0.056 (-0.029, 0.141), 0.197	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.3a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	North America Placebo (N=32)	North America Avapritinib 25 mg (N=52)	Europe Placebo (N=35)	Europe Avapritinib 25 mg (N=71)	P-Value [3]
Infections and infestations, n (%)	3 (9.4)	4 (7.7)	5 (14.3)	13 (18.3)	0.602
Odds Ratio (95% CIs) [1], P-Value		0.806 (0.168, 3.858), 0.786		1.345 (0.438, 4.128), 0.604	
Relative Risk (95% CIs) [2], P-Value		0.821 (0.196, 3.431), 0.786		1.282 (0.496, 3.310), 0.608	
Risk Difference (95% CIs) [2], P-Value		-0.017 (-0.141, 0.107), 0.791		0.040 (-0.106, 0.187), 0.591	
COVID-19, n (%)	3 (9.4)	4 (7.7)	5 (14.3)	13 (18.3)	0.602
Odds Ratio (95% CIs) [1], P-Value		0.806 (0.168, 3.858), 0.786		1.345 (0.438, 4.128), 0.604	
Relative Risk (95% CIs) [2], P-Value		0.821 (0.196, 3.431), 0.786		1.282 (0.496, 3.310), 0.608	
Risk Difference (95% CIs) [2], P-Value		-0.017 (-0.141, 0.107), 0.791		0.040 (-0.106, 0.187), 0.591	
Musculoskeletal and connective tissue disorders, n (%)	3 (9.4)	2 (3.8)	2 (5.7)	9 (12.7)	0.142
Odds Ratio (95% CIs) [1], P-Value		0.387 (0.061, 2.451), 0.298		2.395 (0.489, 11.737), 0.269	
Relative Risk (95% CIs) [2], P-Value		0.410 (0.072, 2.324), 0.314		2.218 (0.506, 9.723), 0.291	
Risk Difference (95% CIs) [2], P-Value		-0.055 (-0.169, 0.058), 0.341		0.070 (-0.039, 0.179), 0.211	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.3a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	North America Placebo (N=32)	North America Avapritinib 25 mg (N=52)	Europe Placebo (N=35)	Europe Avapritinib 25 mg (N=71)	P-Value [3]
Musculoskeletal and connective tissue disorders (cont.)					
Arthralgia, n (%)	3 (9.4)	2 (3.8)	2 (5.7)	9 (12.7)	0.142
Odds Ratio (95% CIs) [1], P-Value		0.387 (0.061, 2.451), 0.298		2.395 (0.489, 11.737), 0.269	
Relative Risk (95% CIs) [2], P-Value		0.410 (0.072, 2.324), 0.314		2.218 (0.506, 9.723), 0.291	
Risk Difference (95% CIs) [2], P-Value		-0.055 (-0.169, 0.058), 0.341		0.070 (-0.039, 0.179), 0.211	
Nervous system disorders, n (%)	7 (21.9)	15 (28.8)	10 (28.6)	18 (25.4)	0.446
Odds Ratio (95% CIs) [1], P-Value		1.448 (0.517, 4.058), 0.480		0.849 (0.343, 2.104), 0.724	
Relative Risk (95% CIs) [2], P-Value		1.319 (0.604, 2.881), 0.488		0.887 (0.459, 1.714), 0.722	
Risk Difference (95% CIs) [2], P-Value		0.070 (-0.119, 0.259), 0.469		-0.032 (-0.213, 0.148), 0.727	
Headache, n (%)	7 (21.9)	11 (21.2)	7 (20.0)	13 (18.3)	0.930
Odds Ratio (95% CIs) [1], P-Value		0.958 (0.329, 2.794), 0.938		0.897 (0.322, 2.495), 0.834	
Relative Risk (95% CIs) [2], P-Value		0.967 (0.418, 2.238), 0.938		0.915 (0.401, 2.089), 0.834	
Risk Difference (95% CIs) [2], P-Value		-0.007 (-0.188, 0.174), 0.938		-0.017 (-0.177, 0.143), 0.836	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.3a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	North America Placebo (N=32)	North America Avapritinib 25 mg (N=52)	Europe Placebo (N=35)	Europe Avapritinib 25 mg (N=71)	P-Value [3]
Nervous system disorders (cont.)					
Dizziness, n (%)	1 (3.1)	6 (11.5)	5 (14.3)	8 (11.3)	0.186
Odds Ratio (95% CIs) [1], P-Value		4.043 (0.464, 35.253), 0.175		0.762 (0.230, 2.527), 0.656	
Relative Risk (95% CIs) [2], P-Value		3.692 (0.466, 29.281), 0.216		0.789 (0.278, 2.235), 0.655	
Risk Difference (95% CIs) [2], P-Value		0.084 (-0.022, 0.190), 0.119		-0.030 (-0.167, 0.107), 0.667	
Skin and subcutaneous tissue disorders, n (%)	1 (3.1)	6 (11.5)	4 (11.4)	4 (5.6)	0.103
Odds Ratio (95% CIs) [1], P-Value		4.043 (0.464, 35.253), 0.175		0.463 (0.109, 1.972), 0.288	
Relative Risk (95% CIs) [2], P-Value		3.692 (0.466, 29.281), 0.216		0.493 (0.131, 1.855), 0.296	
Risk Difference (95% CIs) [2], P-Value		0.084 (-0.022, 0.190), 0.119		-0.058 (-0.176, 0.060), 0.337	
Pruritus, n (%)	1 (3.1)	6 (11.5)	4 (11.4)	4 (5.6)	0.103
Odds Ratio (95% CIs) [1], P-Value		4.043 (0.464, 35.253), 0.175		0.463 (0.109, 1.972), 0.288	
Relative Risk (95% CIs) [2], P-Value		3.692 (0.466, 29.281), 0.216		0.493 (0.131, 1.855), 0.296	
Risk Difference (95% CIs) [2], P-Value		0.084 (-0.022, 0.190), 0.119		-0.058 (-0.176, 0.060), 0.337	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.3a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	North America Placebo (N=32)	North America Avapritinib 25 mg (N=52)	Europe Placebo (N=35)	Europe Avapritinib 25 mg (N=71)	P-Value [3]
Vascular disorders, n (%)	2 (6.3)	2 (3.8)	0	9 (12.7)	0.939
Odds Ratio (95% CIs) [1], P-Value		0.600 (0.080, 4.485), 0.615		NE (NE, NE), 0.028	
Relative Risk (95% CIs) [2], P-Value		0.615 (0.091, 4.155), 0.618		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.024 (-0.123, 0.075), 0.634		0.127 (0.049, 0.204), 0.001	
Flushing, n (%)	2 (6.3)	2 (3.8)	0	9 (12.7)	0.939
Odds Ratio (95% CIs) [1], P-Value		0.600 (0.080, 4.485), 0.615		NE (NE, NE), 0.028	
Relative Risk (95% CIs) [2], P-Value		0.615 (0.091, 4.155), 0.618		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.024 (-0.123, 0.075), 0.634		0.127 (0.049, 0.204), 0.001	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=27)	United States Avapritinib 25 mg (N=44)	Germany Placebo (N=14)	Germany Avapritinib 25 mg (N=17)
Gastrointestinal disorders, n (%)	5 (18.5)	7 (15.9)	3 (21.4)	4 (23.5)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Nausea, n (%)	4 (14.8)	5 (11.4)	3 (21.4)	3 (17.6)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Diarrhoea, n (%)	2 (7.4)	4 (9.1)	0	1 (5.9)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
General disorders and administration site conditions, n (%)	3 (11.1)	8 (18.2)	3 (21.4)	4 (23.5)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=13)	France Placebo (N=5)	France Avapritinib 25 mg (N=10)
Gastrointestinal disorders, n (%)	0	2 (15.4)	1 (20.0)	2 (20.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Nausea, n (%)	0	1 (7.7)	1 (20.0)	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Diarrhoea, n (%)	0	2 (15.4)	0	2 (20.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
General disorders and administration site conditions, n (%)	0	2 (15.4)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=10)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Gastrointestinal disorders, n (%)	1 (20.0)	3 (30.0)	2 (40.0)	2 (25.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Nausea, n (%)	0	2 (20.0)	1 (20.0)	2 (25.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Diarrhoea, n (%)	1 (20.0)	2 (20.0)	2 (40.0)	1 (12.5)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
General disorders and administration site conditions, n (%)	0	3 (30.0)	0	2 (25.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=7)	Norway Placebo (N=2)	Norway Avapritinib 25 mg (N=5)
Gastrointestinal disorders, n (%)	0	3 (42.9)	1 (50.0)	2 (40.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Nausea, n (%)	0	1 (14.3)	1 (50.0)	2 (40.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Diarrhoea, n (%)	0	2 (28.6)	1 (50.0)	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
General disorders and administration site conditions, n (%)	0	0	0	1 (20.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

	Belgium		Italy	
System Organ Class Preferred Term	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=0)	Avapritinib 25 mg (N=3)
Gastrointestinal disorders, n (%)	0	1 (50.0)	0	1 (33.3)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Nausea, n (%)	0	1 (50.0)	0	1 (33.3)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Diarrhoea, n (%)	0	0	0	1 (33.3)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
General disorders and administration site conditions, n (%)	0	1 (50.0)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Switzerland		Sweden	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=1)	Avapritinib 25 mg (N=1)
Gastrointestinal disorders, n (%)	1 (100.0)	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Nausea, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Diarrhoea, n (%)	1 (100.0)	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
General disorders and administration site conditions, n (%)	1 (100.0)	0	1 (100.0)	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Gastrointestinal disorders, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Nausea, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Diarrhoea, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
General disorders and administration site conditions, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=27)	United States Avapritinib 25 mg (N=44)	Germany Placebo (N=14)	Germany Avapritinib 25 mg (N=17)
General disorders and administration site conditions (cont.)	1 (3.7)	5 (11.4)	3 (21.4)	3 (17.6)
Fatigue, n (%)	1 (3.7)	5 (11.4)	3 (21.4)	3 (17.6)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema peripheral, n (%)	2 (7.4)	4 (9.1)	0	1 (5.9)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Infections and infestations, n (%)	2 (7.4)	3 (6.8)	1 (7.1)	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
COVID-19, n (%)	2 (7.4)	3 (6.8)	1 (7.1)	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=13)	France Placebo (N=5)	France Avapritinib 25 mg (N=10)
General disorders and administration site conditions (cont.)	0	0	0	0
Fatigue, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema peripheral, n (%)	0	2 (15.4)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Infections and infestations, n (%)	0	3 (23.1)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
COVID-19, n (%)	0	3 (23.1)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=10)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
General disorders and administration site conditions (cont.)	0	2 (20.0)	0	2 (25.0)
Fatigue, n (%)	0	2 (20.0)	0	2 (25.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema peripheral, n (%)	0	1 (10.0)	0	1 (12.5)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Infections and infestations, n (%)	2 (40.0)	2 (20.0)	1 (20.0)	1 (12.5)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
COVID-19, n (%)	2 (40.0)	2 (20.0)	1 (20.0)	1 (12.5)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=7)	Norway Placebo (N=2)	Norway Avapritinib 25 mg (N=5)
General disorders and administration site conditions (cont.)	0	0	0	0
Fatigue, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema peripheral, n (%)	0	0	0	1 (20.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Infections and infestations, n (%)	0	2 (28.6)	1 (50.0)	3 (60.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
COVID-19, n (%)	0	2 (28.6)	1 (50.0)	3 (60.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=2)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=3)
General disorders and administration site conditions (cont.)	0	0	0	0
Fatigue, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema peripheral, n (%)	0	1 (50.0)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Infections and infestations, n (%)	0	1 (50.0)	0	1 (33.3)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
COVID-19, n (%)	0	1 (50.0)	0	1 (33.3)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Switzerland		Sweden	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=1)	Avapritinib 25 mg (N=1)
General disorders and administration site conditions (cont.)	1 (100.0)	0	0	0
Fatigue, n (%)	1 (100.0)	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema peripheral, n (%)	0	0	1 (100.0)	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Infections and infestations, n (%)	0	0	1 (100.0)	1 (100.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
COVID-19, n (%)	0	0	1 (100.0)	1 (100.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
General disorders and administration site conditions (cont.)	0	0	-
Fatigue, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Oedema peripheral, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Infections and infestations, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
COVID-19, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

	United States		Germany	
System Organ Class Preferred Term	Placebo (N=27)	Avapritinib 25 mg (N=44)	Placebo (N=14)	Avapritinib 25 mg (N=17)
Musculoskeletal and connective tissue disorders, n (%)	3 (11.1)	2 (4.5)	0	1 (5.9)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Arthralgia, n (%)	3 (11.1)	2 (4.5)	0	1 (5.9)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Nervous system disorders, n (%)	4 (14.8)	13 (29.5)	5 (35.7)	5 (29.4)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Headache, n (%)	4 (14.8)	9 (20.5)	3 (21.4)	3 (17.6)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

	Spain		France	
System Organ Class Preferred Term	Placebo (N=3)	Avapritinib 25 mg (N=13)	Placebo (N=5)	Avapritinib 25 mg (N=10)
Musculoskeletal and connective tissue disorders, n (%)	0	1 (7.7)	1 (20.0)	2 (20.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Arthralgia, n (%)	0	1 (7.7)	1 (20.0)	2 (20.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Nervous system disorders, n (%)	0	4 (30.8)	1 (20.0)	1 (10.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Headache, n (%)	0	3 (23.1)	1 (20.0)	1 (10.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

	United Kingdom		Canada	
System Organ Class Preferred Term	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=8)
Musculoskeletal and connective tissue disorders, n (%)	1 (20.0)	1 (10.0)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Arthralgia, n (%)	1 (20.0)	1 (10.0)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Nervous system disorders, n (%)	2 (40.0)	1 (10.0)	3 (60.0)	2 (25.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Headache, n (%)	1 (20.0)	1 (10.0)	3 (60.0)	2 (25.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=7)	Norway Placebo (N=2)	Norway Avapritinib 25 mg (N=5)
Musculoskeletal and connective tissue disorders, n (%)	0	1 (14.3)	0	1 (20.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Arthralgia, n (%)	0	1 (14.3)	0	1 (20.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Nervous system disorders, n (%)	0	2 (28.6)	1 (50.0)	2 (40.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Headache, n (%)	0	1 (14.3)	1 (50.0)	2 (40.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=2)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=3)
Musculoskeletal and connective tissue disorders, n (%)	0	1 (50.0)	0	1 (33.3)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Arthralgia, n (%)	0	1 (50.0)	0	1 (33.3)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Nervous system disorders, n (%)	0	2 (100.0)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Headache, n (%)	0	2 (100.0)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Switzerland		Sweden	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=1)	Avapritinib 25 mg (N=1)
Musculoskeletal and connective tissue disorders, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Arthralgia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Nervous system disorders, n (%)	1 (100.0)	1 (50.0)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Headache, n (%)	1 (100.0)	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Musculoskeletal and connective tissue disorders, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Arthralgia, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Nervous system disorders, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Headache, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=27)	United States Avapritinib 25 mg (N=44)	Germany Placebo (N=14)	Germany Avapritinib 25 mg (N=17)
Nervous system disorders (cont.)	1 (3.7)	6 (13.6)	3 (21.4)	3 (17.6)
Dizziness, n (%)	1 (3.7)	6 (13.6)	3 (21.4)	3 (17.6)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Skin and subcutaneous tissue disorders, n (%)	0	4 (9.1)	1 (7.1)	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Pruritus, n (%)	0	4 (9.1)	1 (7.1)	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Vascular disorders, n (%)	1 (3.7)	0	0	2 (11.8)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=13)	France Placebo (N=5)	France Avapritinib 25 mg (N=10)
Nervous system disorders (cont.)	0	1 (7.7)	0	0
Dizziness, n (%)	0	1 (7.7)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Skin and subcutaneous tissue disorders, n (%)	0	1 (7.7)	1 (20.0)	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Pruritus, n (%)	0	1 (7.7)	1 (20.0)	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Vascular disorders, n (%)	0	1 (7.7)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=10)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Nervous system disorders (cont.)	2 (40.0)	0	0	0
Dizziness, n (%)	2 (40.0)	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Skin and subcutaneous tissue disorders, n (%)	1 (20.0)	1 (10.0)	1 (20.0)	2 (25.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Pruritus, n (%)	1 (20.0)	1 (10.0)	1 (20.0)	2 (25.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Vascular disorders, n (%)	0	2 (20.0)	1 (20.0)	2 (25.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=7)	Norway Placebo (N=2)	Norway Avapritinib 25 mg (N=5)
Nervous system disorders (cont.)	0	2 (28.6)	0	1 (20.0)
Dizziness, n (%)	0	2 (28.6)	0	1 (20.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Skin and subcutaneous tissue disorders, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Pruritus, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Vascular disorders, n (%)	0	0	0	2 (40.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=2)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=3)
Nervous system disorders (cont.)	0	0	0	0
Dizziness, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Skin and subcutaneous tissue disorders, n (%)	1 (100.0)	1 (50.0)	0	1 (33.3)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Pruritus, n (%)	1 (100.0)	1 (50.0)	0	1 (33.3)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Vascular disorders, n (%)	0	1 (50.0)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Switzerland Placebo (N=1)	Switzerland Avapritinib 25 mg (N=2)	Sweden Placebo (N=1)	Sweden Avapritinib 25 mg (N=1)
Nervous system disorders (cont.)	0	1 (50.0)	0	0
Dizziness, n (%)	0	1 (50.0)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Skin and subcutaneous tissue disorders, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Pruritus, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Vascular disorders, n (%)	0	1 (50.0)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Nervous system disorders (cont.)	0	0	-
Dizziness, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Skin and subcutaneous tissue disorders, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Pruritus, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Vascular disorders, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-pp-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.2.1.1.1.2.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=27)	United States Avapritinib 25 mg (N=44)	Germany Placebo (N=14)	Germany Avapritinib 25 mg (N=17)
Vascular disorders (cont.)	1 (3.7)	0	0	2 (11.8)
Flushing, n (%)	1 (3.7)	0	0	2 (11.8)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=13)	France Placebo (N=5)	France Avapritinib 25 mg (N=10)
Vascular disorders (cont.)	0	1 (7.7)	0	0
Flushing, n (%)	0	1 (7.7)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=10)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Vascular disorders (cont.)	0	2 (20.0)	1 (20.0)	2 (25.0)
Flushing, n (%)	0	2 (20.0)	1 (20.0)	2 (25.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=7)	Norway Placebo (N=2)	Norway Avapritinib 25 mg (N=5)
Vascular disorders (cont.)	0	0	0	2 (40.0)
Flushing, n (%)	0	0	0	2 (40.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=2)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=3)
Vascular disorders (cont.)	0	1 (50.0)	0	0
Flushing, n (%)	0	1 (50.0)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Switzerland Placebo (N=1)	Switzerland Avapritinib 25 mg (N=2)	Sweden Placebo (N=1)	Sweden Avapritinib 25 mg (N=1)
Vascular disorders (cont.)	0	1 (50.0)	0	0
Flushing, n (%)	0	1 (50.0)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Vascular disorders (cont.)	0	0	-
Flushing, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.4a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Moderate Placebo (N=22)	Moderate Avapritinib 25 mg (N=37)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=86)	P-Value [3]
Gastrointestinal disorders, n (%)	5 (22.7)	9 (24.3)	9 (20.0)	18 (20.9)	0.968
Odds Ratio (95% CIs) [1], P-Value		1.093 (0.314, 3.808), 0.889		1.059 (0.432, 2.595), 0.901	
Relative Risk (95% CIs) [2], P-Value		1.070 (0.411, 2.788), 0.889		1.047 (0.512, 2.138), 0.901	
Risk Difference (95% CIs) [2], P-Value		0.016 (-0.207, 0.239), 0.888		0.009 (-0.136, 0.154), 0.900	
Nausea, n (%)	4 (18.2)	5 (13.5)	6 (13.3)	13 (15.1)	0.582
Odds Ratio (95% CIs) [1], P-Value		0.703 (0.167, 2.956), 0.630		1.158 (0.408, 3.283), 0.783	
Relative Risk (95% CIs) [2], P-Value		0.743 (0.223, 2.478), 0.629		1.134 (0.462, 2.782), 0.784	
Risk Difference (95% CIs) [2], P-Value		-0.047 (-0.242, 0.149), 0.639		0.018 (-0.107, 0.143), 0.780	
Diarrhoea, n (%)	3 (13.6)	5 (13.5)	4 (8.9)	10 (11.6)	0.758
Odds Ratio (95% CIs) [1], P-Value		0.990 (0.212, 4.615), 0.989		1.349 (0.398, 4.569), 0.630	
Relative Risk (95% CIs) [2], P-Value		0.991 (0.262, 3.749), 0.989		1.308 (0.435, 3.938), 0.633	
Risk Difference (95% CIs) [2], P-Value		-0.001 (-0.182, 0.180), 0.989		0.027 (-0.080, 0.135), 0.617	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.4a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Moderate Placebo (N=22)	Moderate Avapritinib 25 mg (N=37)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=86)	P-Value [3]
General disorders and administration site conditions, n (%)	4 (18.2)	8 (21.6)	4 (8.9)	13 (15.1)	0.672
Odds Ratio (95% CIs) [1], P-Value		1.241 (0.326, 4.725), 0.751		1.825 (0.559, 5.965), 0.314	
Relative Risk (95% CIs) [2], P-Value		1.189 (0.405, 3.495), 0.753		1.701 (0.589, 4.914), 0.327	
Risk Difference (95% CIs) [2], P-Value		0.034 (-0.174, 0.243), 0.747		0.062 (-0.050, 0.175), 0.278	
Fatigue, n (%)	3 (13.6)	4 (10.8)	2 (4.4)	8 (9.3)	0.360
Odds Ratio (95% CIs) [1], P-Value		0.768 (0.155, 3.802), 0.746		2.205 (0.448, 10.852), 0.320	
Relative Risk (95% CIs) [2], P-Value		0.793 (0.195, 3.218), 0.745		2.093 (0.464, 9.446), 0.337	
Risk Difference (95% CIs) [2], P-Value		-0.028 (-0.203, 0.147), 0.751		0.049 (-0.037, 0.135), 0.268	
Oedema peripheral, n (%)	1 (4.5)	4 (10.8)	2 (4.4)	7 (8.1)	0.838
Odds Ratio (95% CIs) [1], P-Value		2.545 (0.266, 24.359), 0.403		1.905 (0.379, 9.576), 0.427	
Relative Risk (95% CIs) [2], P-Value		2.378 (0.284, 19.950), 0.425		1.831 (0.397, 8.454), 0.438	
Risk Difference (95% CIs) [2], P-Value		0.063 (-0.070, 0.195), 0.354		0.037 (-0.047, 0.120), 0.386	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.4a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Moderate Placebo (N=22)	Moderate Avapritinib 25 mg (N=37)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=86)	P-Value [3]
Infections and infestations, n (%)	1 (4.5)	3 (8.1)	7 (15.6)	14 (16.3)	0.663
Odds Ratio (95% CIs) [1], P-Value		1.853 (0.181, 18.999), 0.599		1.056 (0.393, 2.837), 0.915	
Relative Risk (95% CIs) [2], P-Value		1.784 (0.197, 16.112), 0.606		1.047 (0.455, 2.406), 0.915	
Risk Difference (95% CIs) [2], P-Value		0.036 (-0.088, 0.159), 0.573		0.007 (-0.124, 0.139), 0.914	
COVID-19, n (%)	1 (4.5)	3 (8.1)	7 (15.6)	14 (16.3)	0.663
Odds Ratio (95% CIs) [1], P-Value		1.853 (0.181, 18.999), 0.599		1.056 (0.393, 2.837), 0.915	
Relative Risk (95% CIs) [2], P-Value		1.784 (0.197, 16.112), 0.606		1.047 (0.455, 2.406), 0.915	
Risk Difference (95% CIs) [2], P-Value		0.036 (-0.088, 0.159), 0.573		0.007 (-0.124, 0.139), 0.914	
Musculoskeletal and connective tissue disorders, n (%)	1 (4.5)	5 (13.5)	4 (8.9)	6 (7.0)	0.270
Odds Ratio (95% CIs) [1], P-Value		3.281 (0.358, 30.105), 0.270		0.769 (0.205, 2.878), 0.696	
Relative Risk (95% CIs) [2], P-Value		2.973 (0.371, 23.825), 0.305		0.785 (0.233, 2.639), 0.695	
Risk Difference (95% CIs) [2], P-Value		0.090 (-0.051, 0.230), 0.211		-0.019 (-0.118, 0.080), 0.705	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.4a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Moderate Placebo (N=22)	Moderate Avapritinib 25 mg (N=37)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=86)	P-Value [3]
Musculoskeletal and connective tissue disorders (cont.)					
Arthralgia, n (%)	1 (4.5)	5 (13.5)	4 (8.9)	6 (7.0)	0.270
Odds Ratio (95% CIs) [1], P-Value		3.281 (0.358, 30.105), 0.270		0.769 (0.205, 2.878), 0.696	
Relative Risk (95% CIs) [2], P-Value		2.973 (0.371, 23.825), 0.305		0.785 (0.233, 2.639), 0.695	
Risk Difference (95% CIs) [2], P-Value		0.090 (-0.051, 0.230), 0.211		-0.019 (-0.118, 0.080), 0.705	
Nervous system disorders, n (%)	6 (27.3)	7 (18.9)	11 (24.4)	26 (30.2)	0.314
Odds Ratio (95% CIs) [1], P-Value		0.622 (0.179, 2.167), 0.454		1.339 (0.589, 3.044), 0.485	
Relative Risk (95% CIs) [2], P-Value		0.694 (0.267, 1.801), 0.453		1.237 (0.675, 2.267), 0.492	
Risk Difference (95% CIs) [2], P-Value		-0.084 (-0.308, 0.141), 0.467		0.058 (-0.101, 0.217), 0.475	
Headache, n (%)	5 (22.7)	5 (13.5)	9 (20.0)	19 (22.1)	0.363
Odds Ratio (95% CIs) [1], P-Value		0.531 (0.135, 2.095), 0.362		1.134 (0.466, 2.764), 0.781	
Relative Risk (95% CIs) [2], P-Value		0.595 (0.194, 1.825), 0.364		1.105 (0.545, 2.239), 0.782	
Risk Difference (95% CIs) [2], P-Value		-0.092 (-0.299, 0.115), 0.383		0.021 (-0.125, 0.167), 0.779	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.4a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Moderate Placebo (N=22)	Moderate Avapritinib 25 mg (N=37)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=86)	P-Value [3]
Nervous system disorders (cont.)					
Dizziness, n (%)	1 (4.5)	4 (10.8)	5 (11.1)	10 (11.6)	0.494
Odds Ratio (95% CIs) [1], P-Value		2.545 (0.266, 24.359), 0.403		1.053 (0.337, 3.290), 0.930	
Relative Risk (95% CIs) [2], P-Value		2.378 (0.284, 19.950), 0.425		1.047 (0.381, 2.877), 0.930	
Risk Difference (95% CIs) [2], P-Value		0.063 (-0.070, 0.195), 0.354		0.005 (-0.109, 0.119), 0.929	
Skin and subcutaneous tissue disorders, n (%)	1 (4.5)	2 (5.4)	4 (8.9)	8 (9.3)	0.925
Odds Ratio (95% CIs) [1], P-Value		1.200 (0.102, 14.055), 0.884		1.051 (0.299, 3.700), 0.938	
Relative Risk (95% CIs) [2], P-Value		1.189 (0.114, 12.367), 0.885		1.047 (0.333, 3.288), 0.938	
Risk Difference (95% CIs) [2], P-Value		0.009 (-0.105, 0.122), 0.882		0.004 (-0.099, 0.107), 0.938	
Pruritus, n (%)	1 (4.5)	2 (5.4)	4 (8.9)	8 (9.3)	0.925
Odds Ratio (95% CIs) [1], P-Value		1.200 (0.102, 14.055), 0.884		1.051 (0.299, 3.700), 0.938	
Relative Risk (95% CIs) [2], P-Value		1.189 (0.114, 12.367), 0.885		1.047 (0.333, 3.288), 0.938	
Risk Difference (95% CIs) [2], P-Value		0.009 (-0.105, 0.122), 0.882		0.004 (-0.099, 0.107), 0.938	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.2.1.1.1.2.4a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Moderate Placebo (N=22)	Moderate Avapritinib 25 mg (N=37)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=86)	P-Value [3]
Vascular disorders, n (%)	1 (4.5)	5 (13.5)	1 (2.2)	6 (7.0)	0.997
Odds Ratio (95% CIs) [1], P-Value		3.281 (0.358, 30.105), 0.270		3.300 (0.385, 28.294), 0.251	
Relative Risk (95% CIs) [2], P-Value		2.973 (0.371, 23.825), 0.305		3.140 (0.390, 25.283), 0.282	
Risk Difference (95% CIs) [2], P-Value		0.090 (-0.051, 0.230), 0.211		0.048 (-0.021, 0.116), 0.177	
Flushing, n (%)	1 (4.5)	5 (13.5)	1 (2.2)	6 (7.0)	0.997
Odds Ratio (95% CIs) [1], P-Value		3.281 (0.358, 30.105), 0.270		3.300 (0.385, 28.294), 0.251	
Relative Risk (95% CIs) [2], P-Value		2.973 (0.371, 23.825), 0.305		3.140 (0.390, 25.283), 0.282	
Risk Difference (95% CIs) [2], P-Value		0.090 (-0.051, 0.230), 0.211		0.048 (-0.021, 0.116), 0.177	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.5a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	<20 ng/mL Placebo (N=13)	<20 ng/mL Avapritinib 25 mg (N=26)	>=20 ng/mL Placebo (N=54)	>=20 ng/mL Avapritinib 25 mg (N=97)	P-Value [3]
Gastrointestinal disorders, n (%)	3 (23.1)	8 (30.8)	11 (20.4)	19 (19.6)	0.620
Odds Ratio (95% CIs) [1], P-Value		1.481 (0.319, 6.881), 0.615		0.952 (0.415, 2.185), 0.908	
Relative Risk (95% CIs) [2], P-Value		1.333 (0.423, 4.202), 0.623		0.962 (0.495, 1.868), 0.908	
Risk Difference (95% CIs) [2], P-Value		0.077 (-0.213, 0.367), 0.603		-0.008 (-0.141, 0.126), 0.908	
Nausea, n (%)	2 (15.4)	7 (26.9)	8 (14.8)	11 (11.3)	0.319
Odds Ratio (95% CIs) [1], P-Value		2.026 (0.356, 11.522), 0.420		0.735 (0.276, 1.957), 0.537	
Relative Risk (95% CIs) [2], P-Value		1.750 (0.422, 7.265), 0.441		0.765 (0.328, 1.787), 0.537	
Risk Difference (95% CIs) [2], P-Value		0.115 (-0.144, 0.375), 0.384		-0.035 (-0.149, 0.079), 0.550	
Diarrhoea, n (%)	1 (7.7)	4 (15.4)	6 (11.1)	11 (11.3)	0.558
Odds Ratio (95% CIs) [1], P-Value		2.182 (0.218, 21.793), 0.498		1.023 (0.356, 2.940), 0.966	
Relative Risk (95% CIs) [2], P-Value		2.000 (0.248, 16.133), 0.515		1.021 (0.400, 2.606), 0.966	
Risk Difference (95% CIs) [2], P-Value		0.077 (-0.124, 0.277), 0.452		0.002 (-0.103, 0.107), 0.966	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.5a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	<20 ng/mL Placebo (N=13)	<20 ng/mL Avapritinib 25 mg (N=26)	>=20 ng/mL Placebo (N=54)	>=20 ng/mL Avapritinib 25 mg (N=97)	P-Value [3]
General disorders and administration site conditions, n (%)	1 (7.7)	6 (23.1)	7 (13.0)	15 (15.5)	0.387
Odds Ratio (95% CIs) [1], P-Value		3.600 (0.385, 33.637), 0.238		1.228 (0.467, 3.228), 0.676	
Relative Risk (95% CIs) [2], P-Value		3.000 (0.402, 22.381), 0.284		1.193 (0.519, 2.744), 0.678	
Risk Difference (95% CIs) [2], P-Value		0.154 (-0.063, 0.371), 0.165		0.025 (-0.090, 0.140), 0.670	
Fatigue, n (%)	0	4 (15.4)	5 (9.3)	8 (8.2)	0.959
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.135		0.881 (0.273, 2.840), 0.832	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.891 (0.307, 2.588), 0.832	
Risk Difference (95% CIs) [2], P-Value		0.154 (0.015, 0.293), 0.030		-0.010 (-0.105, 0.085), 0.834	
Oedema peripheral, n (%)	1 (7.7)	2 (7.7)	2 (3.7)	9 (9.3)	0.516
Odds Ratio (95% CIs) [1], P-Value		1.000 (0.082, 12.164), >0.999		2.659 (0.553, 12.782), 0.206	
Relative Risk (95% CIs) [2], P-Value		1.000 (0.100, 10.037), >0.999		2.505 (0.561, 11.178), 0.229	
Risk Difference (95% CIs) [2], P-Value		0.000 (-0.177, 0.177), >0.999		0.056 (-0.021, 0.132), 0.154	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.5a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	<20 ng/mL Placebo (N=13)	<20 ng/mL Avapritinib 25 mg (N=26)	>=20 ng/mL Placebo (N=54)	>=20 ng/mL Avapritinib 25 mg (N=97)	P-Value [3]
Infections and infestations, n (%)	1 (7.7)	4 (15.4)	7 (13.0)	13 (13.4)	0.561
Odds Ratio (95% CIs) [1], P-Value		2.182 (0.218, 21.793), 0.498		1.039 (0.388, 2.785), 0.939	
Relative Risk (95% CIs) [2], P-Value		2.000 (0.248, 16.133), 0.515		1.034 (0.439, 2.435), 0.939	
Risk Difference (95% CIs) [2], P-Value		0.077 (-0.124, 0.277), 0.452		0.004 (-0.108, 0.117), 0.939	
COVID-19, n (%)	1 (7.7)	4 (15.4)	7 (13.0)	13 (13.4)	0.561
Odds Ratio (95% CIs) [1], P-Value		2.182 (0.218, 21.793), 0.498		1.039 (0.388, 2.785), 0.939	
Relative Risk (95% CIs) [2], P-Value		2.000 (0.248, 16.133), 0.515		1.034 (0.439, 2.435), 0.939	
Risk Difference (95% CIs) [2], P-Value		0.077 (-0.124, 0.277), 0.452		0.004 (-0.108, 0.117), 0.939	
Musculoskeletal and connective tissue disorders, n (%)	1 (7.7)	5 (19.2)	4 (7.4)	6 (6.2)	0.351
Odds Ratio (95% CIs) [1], P-Value		2.857 (0.298, 27.412), 0.346		0.824 (0.222, 3.059), 0.772	
Relative Risk (95% CIs) [2], P-Value		2.500 (0.325, 19.250), 0.379		0.835 (0.246, 2.830), 0.772	
Risk Difference (95% CIs) [2], P-Value		0.115 (-0.094, 0.325), 0.281		-0.012 (-0.097, 0.073), 0.777	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.5a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	<20 ng/mL Placebo (N=13)	<20 ng/mL Avapritinib 25 mg (N=26)	>=20 ng/mL Placebo (N=54)	>=20 ng/mL Avapritinib 25 mg (N=97)	P-Value [3]
Musculoskeletal and connective tissue disorders (cont.)					
Arthralgia, n (%)	1 (7.7)	5 (19.2)	4 (7.4)	6 (6.2)	0.351
Odds Ratio (95% CIs) [1], P-Value		2.857 (0.298, 27.412), 0.346		0.824 (0.222, 3.059), 0.772	
Relative Risk (95% CIs) [2], P-Value		2.500 (0.325, 19.250), 0.379		0.835 (0.246, 2.830), 0.772	
Risk Difference (95% CIs) [2], P-Value		0.115 (-0.094, 0.325), 0.281		-0.012 (-0.097, 0.073), 0.777	
Nervous system disorders, n (%)	3 (23.1)	8 (30.8)	14 (25.9)	25 (25.8)	0.646
Odds Ratio (95% CIs) [1], P-Value		1.481 (0.319, 6.881), 0.615		0.992 (0.464, 2.121), 0.984	
Relative Risk (95% CIs) [2], P-Value		1.333 (0.423, 4.202), 0.623		0.994 (0.566, 1.746), 0.984	
Risk Difference (95% CIs) [2], P-Value		0.077 (-0.213, 0.367), 0.603		-0.002 (-0.147, 0.144), 0.984	
Headache, n (%)	3 (23.1)	6 (23.1)	11 (20.4)	18 (18.6)	0.899
Odds Ratio (95% CIs) [1], P-Value		1.000 (0.206, 4.856), >0.999		0.891 (0.386, 2.057), 0.786	
Relative Risk (95% CIs) [2], P-Value		1.000 (0.297, 3.372), >0.999		0.911 (0.465, 1.784), 0.786	
Risk Difference (95% CIs) [2], P-Value		0.000 (-0.281, 0.281), >0.999		-0.018 (-0.151, 0.114), 0.788	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.5a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	<20 ng/mL Placebo (N=13)	<20 ng/mL Avapritinib 25 mg (N=26)	>=20 ng/mL Placebo (N=54)	>=20 ng/mL Avapritinib 25 mg (N=97)	P-Value [3]
Nervous system disorders (cont.)					
Dizziness, n (%)	1 (7.7)	4 (15.4)	5 (9.3)	10 (10.3)	0.613
Odds Ratio (95% CIs) [1], P-Value		2.182 (0.218, 21.793), 0.498		1.126 (0.364, 3.484), 0.836	
Relative Risk (95% CIs) [2], P-Value		2.000 (0.248, 16.133), 0.515		1.113 (0.401, 3.090), 0.837	
Risk Difference (95% CIs) [2], P-Value		0.077 (-0.124, 0.277), 0.452		0.011 (-0.088, 0.109), 0.834	
Skin and subcutaneous tissue disorders, n (%)	3 (23.1)	2 (7.7)	2 (3.7)	8 (8.2)	0.095
Odds Ratio (95% CIs) [1], P-Value		0.278 (0.040, 1.924), 0.176		2.337 (0.478, 11.424), 0.282	
Relative Risk (95% CIs) [2], P-Value		0.333 (0.063, 1.754), 0.195		2.227 (0.490, 10.114), 0.300	
Risk Difference (95% CIs) [2], P-Value		-0.154 (-0.405, 0.097), 0.229		0.045 (-0.029, 0.120), 0.231	
Pruritus, n (%)	3 (23.1)	2 (7.7)	2 (3.7)	8 (8.2)	0.095
Odds Ratio (95% CIs) [1], P-Value		0.278 (0.040, 1.924), 0.176		2.337 (0.478, 11.424), 0.282	
Relative Risk (95% CIs) [2], P-Value		0.333 (0.063, 1.754), 0.195		2.227 (0.490, 10.114), 0.300	
Risk Difference (95% CIs) [2], P-Value		-0.154 (-0.405, 0.097), 0.229		0.045 (-0.029, 0.120), 0.231	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.5a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	<20 ng/mL Placebo (N=13)	<20 ng/mL Avapritinib 25 mg (N=26)	>=20 ng/mL Placebo (N=54)	>=20 ng/mL Avapritinib 25 mg (N=97)	P-Value [3]
Vascular disorders, n (%)	0	3 (11.5)	2 (3.7)	8 (8.2)	0.967
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.202		2.337 (0.478, 11.424), 0.282	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		2.227 (0.490, 10.114), 0.300	
Risk Difference (95% CIs) [2], P-Value		0.115 (-0.007, 0.238), 0.066		0.045 (-0.029, 0.120), 0.231	
Flushing, n (%)	0	3 (11.5)	2 (3.7)	8 (8.2)	0.967
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.202		2.337 (0.478, 11.424), 0.282	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		2.227 (0.490, 10.114), 0.300	
Risk Difference (95% CIs) [2], P-Value		0.115 (-0.007, 0.238), 0.066		0.045 (-0.029, 0.120), 0.231	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.6a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Number of Baseline BSC <4		Number of Baseline BSC >=4		P-Value [3]
	Placebo (N=32)	Avapritinib 25 mg (N=63)	Placebo (N=35)	Avapritinib 25 mg (N=60)	
Gastrointestinal disorders, n (%)	7 (21.9)	15 (23.8)	7 (20.0)	12 (20.0)	0.883
Odds Ratio (95% CIs) [1], P-Value		1.116 (0.403, 3.092), 0.833		1.000 (0.353, 2.835), >0.999	
Relative Risk (95% CIs) [2], P-Value		1.088 (0.494, 2.398), 0.833		1.000 (0.434, 2.302), >0.999	
Risk Difference (95% CIs) [2], P-Value		0.019 (-0.158, 0.197), 0.831		0.000 (-0.167, 0.167), >0.999	
Nausea, n (%)	6 (18.8)	9 (14.3)	4 (11.4)	9 (15.0)	0.460
Odds Ratio (95% CIs) [1], P-Value		0.722 (0.232, 2.245), 0.573		1.368 (0.388, 4.819), 0.625	
Relative Risk (95% CIs) [2], P-Value		0.762 (0.297, 1.953), 0.571		1.313 (0.436, 3.949), 0.628	
Risk Difference (95% CIs) [2], P-Value		-0.045 (-0.205, 0.116), 0.586		0.036 (-0.103, 0.175), 0.614	
Diarrhoea, n (%)	2 (6.3)	7 (11.1)	5 (14.3)	8 (13.3)	0.494
Odds Ratio (95% CIs) [1], P-Value		1.875 (0.366, 9.597), 0.444		0.923 (0.277, 3.078), 0.896	
Relative Risk (95% CIs) [2], P-Value		1.778 (0.392, 8.070), 0.456		0.933 (0.331, 2.632), 0.896	
Risk Difference (95% CIs) [2], P-Value		0.049 (-0.066, 0.163), 0.404		-0.010 (-0.154, 0.135), 0.897	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.6a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Number of Baseline BSC <4 Placebo (N=32)	Number of Baseline BSC <4 Avapritinib 25 mg (N=63)	Number of Baseline BSC >=4 Placebo (N=35)	Number of Baseline BSC >=4 Avapritinib 25 mg (N=60)	P-Value [3]
General disorders and administration site conditions, n (%)	4 (12.5)	11 (17.5)	4 (11.4)	10 (16.7)	0.959
Odds Ratio (95% CIs) [1], P-Value		1.481 (0.431, 5.082), 0.531		1.550 (0.447, 5.373), 0.487	
Relative Risk (95% CIs) [2], P-Value		1.397 (0.483, 4.041), 0.538		1.458 (0.494, 4.303), 0.494	
Risk Difference (95% CIs) [2], P-Value		0.050 (-0.098, 0.198), 0.511		0.052 (-0.089, 0.194), 0.468	
Fatigue, n (%)	3 (9.4)	6 (9.5)	2 (5.7)	6 (10.0)	0.601
Odds Ratio (95% CIs) [1], P-Value		1.018 (0.237, 4.365), 0.981		1.833 (0.349, 9.622), 0.468	
Relative Risk (95% CIs) [2], P-Value		1.016 (0.272, 3.799), 0.981		1.750 (0.373, 8.204), 0.478	
Risk Difference (95% CIs) [2], P-Value		0.001 (-0.123, 0.126), 0.981		0.043 (-0.065, 0.151), 0.437	
Oedema peripheral, n (%)	1 (3.1)	5 (7.9)	2 (5.7)	6 (10.0)	0.788
Odds Ratio (95% CIs) [1], P-Value		2.672 (0.299, 23.899), 0.362		1.833 (0.349, 9.622), 0.468	
Relative Risk (95% CIs) [2], P-Value		2.540 (0.310, 20.832), 0.385		1.750 (0.373, 8.204), 0.478	
Risk Difference (95% CIs) [2], P-Value		0.048 (-0.042, 0.138), 0.294		0.043 (-0.065, 0.151), 0.437	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.6a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Number of Baseline BSC <4 Placebo (N=32)	 Avapritinib 25 mg (N=63)	Number of Baseline BSC >=4 Placebo (N=35)	 Avapritinib 25 mg (N=60)	P-Value [3]
Infections and infestations, n (%)	2 (6.3)	8 (12.7)	6 (17.1)	9 (15.0)	0.350
Odds Ratio (95% CIs) [1], P-Value		2.182 (0.435, 10.938), 0.333		0.853 (0.276, 2.638), 0.782	
Relative Risk (95% CIs) [2], P-Value		2.032 (0.458, 9.014), 0.351		0.875 (0.340, 2.252), 0.782	
Risk Difference (95% CIs) [2], P-Value		0.064 (-0.053, 0.182), 0.282		-0.021 (-0.176, 0.133), 0.785	
COVID-19, n (%)	2 (6.3)	8 (12.7)	6 (17.1)	9 (15.0)	0.350
Odds Ratio (95% CIs) [1], P-Value		2.182 (0.435, 10.938), 0.333		0.853 (0.276, 2.638), 0.782	
Relative Risk (95% CIs) [2], P-Value		2.032 (0.458, 9.014), 0.351		0.875 (0.340, 2.252), 0.782	
Risk Difference (95% CIs) [2], P-Value		0.064 (-0.053, 0.182), 0.282		-0.021 (-0.176, 0.133), 0.785	
Musculoskeletal and connective tissue disorders, n (%)	1 (3.1)	8 (12.7)	4 (11.4)	3 (5.0)	0.074
Odds Ratio (95% CIs) [1], P-Value		4.509 (0.539, 37.752), 0.132		0.408 (0.086, 1.940), 0.247	
Relative Risk (95% CIs) [2], P-Value		4.063 (0.531, 31.090), 0.177		0.438 (0.104, 1.842), 0.260	
Risk Difference (95% CIs) [2], P-Value		0.096 (-0.006, 0.198), 0.066		-0.064 (-0.183, 0.055), 0.290	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.6a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Number of Baseline BSC <4 Placebo (N=32)	 Avapritinib 25 mg (N=63)	Number of Baseline BSC >=4 Placebo (N=35)	 Avapritinib 25 mg (N=60)	P-Value [3]
Musculoskeletal and connective tissue disorders (cont.)					
Arthralgia, n (%)	1 (3.1)	8 (12.7)	4 (11.4)	3 (5.0)	0.074
Odds Ratio (95% CIs) [1], P-Value		4.509 (0.539, 37.752), 0.132		0.408 (0.086, 1.940), 0.247	
Relative Risk (95% CIs) [2], P-Value		4.063 (0.531, 31.090), 0.177		0.438 (0.104, 1.842), 0.260	
Risk Difference (95% CIs) [2], P-Value		0.096 (-0.006, 0.198), 0.066		-0.064 (-0.183, 0.055), 0.290	
Nervous system disorders, n (%)	11 (34.4)	16 (25.4)	6 (17.1)	17 (28.3)	0.129
Odds Ratio (95% CIs) [1], P-Value		0.650 (0.258, 1.638), 0.359		1.911 (0.673, 5.423), 0.219	
Relative Risk (95% CIs) [2], P-Value		0.739 (0.390, 1.400), 0.353		1.653 (0.719, 3.798), 0.237	
Risk Difference (95% CIs) [2], P-Value		-0.090 (-0.286, 0.107), 0.371		0.112 (-0.057, 0.281), 0.195	
Headache, n (%)	9 (28.1)	13 (20.6)	5 (14.3)	11 (18.3)	0.360
Odds Ratio (95% CIs) [1], P-Value		0.664 (0.249, 1.776), 0.413		1.347 (0.426, 4.257), 0.611	
Relative Risk (95% CIs) [2], P-Value		0.734 (0.352, 1.531), 0.409		1.283 (0.486, 3.390), 0.615	
Risk Difference (95% CIs) [2], P-Value		-0.075 (-0.260, 0.110), 0.428		0.040 (-0.111, 0.192), 0.601	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.6a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Number of Baseline BSC <4 Placebo (N=32)	 Avapritinib 25 mg (N=63)	Number of Baseline BSC >=4 Placebo (N=35)	 Avapritinib 25 mg (N=60)	P-Value [3]
Nervous system disorders (cont.)					
Dizziness, n (%)	4 (12.5)	5 (7.9)	2 (5.7)	9 (15.0)	0.145
Odds Ratio (95% CIs) [1], P-Value		0.603 (0.150, 2.423), 0.473		2.912 (0.592, 14.329), 0.172	
Relative Risk (95% CIs) [2], P-Value		0.635 (0.183, 2.203), 0.474		2.625 (0.601, 11.467), 0.200	
Risk Difference (95% CIs) [2], P-Value		-0.046 (-0.178, 0.087), 0.500		0.093 (-0.026, 0.212), 0.125	
Skin and subcutaneous tissue disorders, n (%)	3 (9.4)	3 (4.8)	2 (5.7)	7 (11.7)	0.205
Odds Ratio (95% CIs) [1], P-Value		0.483 (0.092, 2.543), 0.382		2.179 (0.427, 11.128), 0.339	
Relative Risk (95% CIs) [2], P-Value		0.508 (0.109, 2.376), 0.389		2.042 (0.449, 9.290), 0.356	
Risk Difference (95% CIs) [2], P-Value		-0.046 (-0.160, 0.068), 0.427		0.060 (-0.052, 0.171), 0.297	
Pruritus, n (%)	3 (9.4)	3 (4.8)	2 (5.7)	7 (11.7)	0.205
Odds Ratio (95% CIs) [1], P-Value		0.483 (0.092, 2.543), 0.382		2.179 (0.427, 11.128), 0.339	
Relative Risk (95% CIs) [2], P-Value		0.508 (0.109, 2.376), 0.389		2.042 (0.449, 9.290), 0.356	
Risk Difference (95% CIs) [2], P-Value		-0.046 (-0.160, 0.068), 0.427		0.060 (-0.052, 0.171), 0.297	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.6a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Number of Baseline BSC <4		Number of Baseline BSC >=4		P-Value [3]
	Placebo (N=32)	Avapritinib 25 mg (N=63)	Placebo (N=35)	Avapritinib 25 mg (N=60)	
Vascular disorders, n (%)	0	6 (9.5)	2 (5.7)	5 (8.3)	0.948
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.071		1.500 (0.275, 8.175), 0.637	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.458 (0.299, 7.122), 0.641	
Risk Difference (95% CIs) [2], P-Value		0.095 (0.023, 0.168), 0.010		0.026 (-0.078, 0.130), 0.621	
Flushing, n (%)	0	6 (9.5)	2 (5.7)	5 (8.3)	0.948
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.071		1.500 (0.275, 8.175), 0.637	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.458 (0.299, 7.122), 0.641	
Risk Difference (95% CIs) [2], P-Value		0.095 (0.023, 0.168), 0.010		0.026 (-0.078, 0.130), 0.621	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.7a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Yes Placebo (N=6)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=61)	No Avapritinib 25 mg (N=104)	P-Value [3]
Gastrointestinal disorders, n (%)	1 (16.7)	2 (10.5)	13 (21.3)	25 (24.0)	0.619
Odds Ratio (95% CIs) [1], P-Value		0.588 (0.044, 7.914), 0.687		1.168 (0.546, 2.499), 0.688	
Relative Risk (95% CIs) [2], P-Value		0.632 (0.069, 5.804), 0.685		1.128 (0.625, 2.037), 0.690	
Risk Difference (95% CIs) [2], P-Value		-0.061 (-0.390, 0.267), 0.714		0.027 (-0.104, 0.159), 0.685	
Nausea, n (%)	0	1 (5.3)	10 (16.4)	17 (16.3)	0.956
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.566		0.997 (0.424, 2.341), 0.994	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.997 (0.488, 2.037), 0.994	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		-0.000 (-0.117, 0.116), 0.994	
Diarrhoea, n (%)	1 (16.7)	2 (10.5)	6 (9.8)	13 (12.5)	0.574
Odds Ratio (95% CIs) [1], P-Value		0.588 (0.044, 7.914), 0.687		1.310 (0.471, 3.645), 0.605	
Relative Risk (95% CIs) [2], P-Value		0.632 (0.069, 5.804), 0.685		1.271 (0.509, 3.171), 0.607	
Risk Difference (95% CIs) [2], P-Value		-0.061 (-0.390, 0.267), 0.714		0.027 (-0.071, 0.125), 0.595	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.7a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Yes Placebo (N=6)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=61)	No Avapritinib 25 mg (N=104)	P-Value [3]
General disorders and administration site conditions, n (%)	0	2 (10.5)	8 (13.1)	19 (18.3)	0.954
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.407		1.481 (0.605, 3.622), 0.388	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.393 (0.649, 2.988), 0.395	
Risk Difference (95% CIs) [2], P-Value		0.105 (-0.033, 0.243), 0.135		0.052 (-0.061, 0.164), 0.370	
Fatigue, n (%)	0	1 (5.3)	5 (8.2)	11 (10.6)	0.964
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.566		1.325 (0.437, 4.011), 0.618	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.290 (0.471, 3.539), 0.620	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		0.024 (-0.067, 0.115), 0.607	
Oedema peripheral, n (%)	0	2 (10.5)	3 (4.9)	9 (8.7)	0.965
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.407		1.832 (0.476, 7.043), 0.372	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.760 (0.495, 6.252), 0.382	
Risk Difference (95% CIs) [2], P-Value		0.105 (-0.033, 0.243), 0.135		0.037 (-0.039, 0.114), 0.339	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.7a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Yes Placebo (N=6)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=61)	No Avapritinib 25 mg (N=104)	P-Value [3]
Infections and infestations, n (%)	1 (16.7)	1 (5.3)	7 (11.5)	16 (15.4)	0.305
Odds Ratio (95% CIs) [1], P-Value		0.278 (0.015, 5.273), 0.369		1.403 (0.542, 3.629), 0.484	
Relative Risk (95% CIs) [2], P-Value		0.316 (0.023, 4.318), 0.388		1.341 (0.585, 3.075), 0.489	
Risk Difference (95% CIs) [2], P-Value		-0.114 (-0.429, 0.201), 0.477		0.039 (-0.067, 0.145), 0.469	
COVID-19, n (%)	1 (16.7)	1 (5.3)	7 (11.5)	16 (15.4)	0.305
Odds Ratio (95% CIs) [1], P-Value		0.278 (0.015, 5.273), 0.369		1.403 (0.542, 3.629), 0.484	
Relative Risk (95% CIs) [2], P-Value		0.316 (0.023, 4.318), 0.388		1.341 (0.585, 3.075), 0.489	
Risk Difference (95% CIs) [2], P-Value		-0.114 (-0.429, 0.201), 0.477		0.039 (-0.067, 0.145), 0.469	
Musculoskeletal and connective tissue disorders, n (%)	1 (16.7)	2 (10.5)	4 (6.6)	9 (8.7)	0.571
Odds Ratio (95% CIs) [1], P-Value		0.588 (0.044, 7.914), 0.687		1.350 (0.397, 4.585), 0.629	
Relative Risk (95% CIs) [2], P-Value		0.632 (0.069, 5.804), 0.685		1.320 (0.424, 4.104), 0.632	
Risk Difference (95% CIs) [2], P-Value		-0.061 (-0.390, 0.267), 0.714		0.021 (-0.061, 0.103), 0.618	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.7a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
System Organ Class Preferred Term	Placebo (N=6)	Avapritinib 25 mg (N=19)	Placebo (N=61)	Avapritinib 25 mg (N=104)	P-Value [3]
Musculoskeletal and connective tissue disorders (cont.)					
Arthralgia, n (%)	1 (16.7)	2 (10.5)	4 (6.6)	9 (8.7)	0.571
Odds Ratio (95% CIs) [1], P-Value		0.588 (0.044, 7.914), 0.687		1.350 (0.397, 4.585), 0.629	
Relative Risk (95% CIs) [2], P-Value		0.632 (0.069, 5.804), 0.685		1.320 (0.424, 4.104), 0.632	
Risk Difference (95% CIs) [2], P-Value		-0.061 (-0.390, 0.267), 0.714		0.021 (-0.061, 0.103), 0.618	
Nervous system disorders, n (%)	1 (16.7)	2 (10.5)	16 (26.2)	31 (29.8)	0.607
Odds Ratio (95% CIs) [1], P-Value		0.588 (0.044, 7.914), 0.687		1.194 (0.588, 2.426), 0.623	
Relative Risk (95% CIs) [2], P-Value		0.632 (0.069, 5.804), 0.685		1.136 (0.680, 1.900), 0.626	
Risk Difference (95% CIs) [2], P-Value		-0.061 (-0.390, 0.267), 0.714		0.036 (-0.105, 0.177), 0.619	
Headache, n (%)	1 (16.7)	1 (5.3)	13 (21.3)	23 (22.1)	0.392
Odds Ratio (95% CIs) [1], P-Value		0.278 (0.015, 5.273), 0.369		1.048 (0.486, 2.260), 0.904	
Relative Risk (95% CIs) [2], P-Value		0.316 (0.023, 4.318), 0.388		1.038 (0.568, 1.895), 0.904	
Risk Difference (95% CIs) [2], P-Value		-0.114 (-0.429, 0.201), 0.477		0.008 (-0.122, 0.138), 0.904	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.7a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Yes Placebo (N=6)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=61)	No Avapritinib 25 mg (N=104)	P-Value [3]
Nervous system disorders (cont.)					
Dizziness, n (%)	0	1 (5.3)	6 (9.8)	13 (12.5)	0.962
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.566		1.310 (0.471, 3.645), 0.605	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.271 (0.509, 3.171), 0.607	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		0.027 (-0.071, 0.125), 0.595	
Skin and subcutaneous tissue disorders, n (%)	2 (33.3)	2 (10.5)	3 (4.9)	8 (7.7)	0.151
Odds Ratio (95% CIs) [1], P-Value		0.235 (0.025, 2.215), 0.184		1.611 (0.411, 6.317), 0.490	
Relative Risk (95% CIs) [2], P-Value		0.316 (0.056, 1.784), 0.192		1.564 (0.431, 5.675), 0.496	
Risk Difference (95% CIs) [2], P-Value		-0.228 (-0.630, 0.174), 0.266		0.028 (-0.047, 0.102), 0.466	
Pruritus, n (%)	2 (33.3)	2 (10.5)	3 (4.9)	8 (7.7)	0.151
Odds Ratio (95% CIs) [1], P-Value		0.235 (0.025, 2.215), 0.184		1.611 (0.411, 6.317), 0.490	
Relative Risk (95% CIs) [2], P-Value		0.316 (0.056, 1.784), 0.192		1.564 (0.431, 5.675), 0.496	
Risk Difference (95% CIs) [2], P-Value		-0.228 (-0.630, 0.174), 0.266		0.028 (-0.047, 0.102), 0.466	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.7a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Yes Placebo (N=6)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=61)	No Avapritinib 25 mg (N=104)	P-Value [3]
Vascular disorders, n (%)	0	1 (5.3)	2 (3.3)	10 (9.6)	0.957
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.566		3.138 (0.664, 14.826), 0.130	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		2.933 (0.664, 12.947), 0.156	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		0.063 (-0.009, 0.136), 0.085	
Flushing, n (%)	0	1 (5.3)	2 (3.3)	10 (9.6)	0.957
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.566		3.138 (0.664, 14.826), 0.130	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		2.933 (0.664, 12.947), 0.156	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		0.063 (-0.009, 0.136), 0.085	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.8a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Yes		No		P-Value [3]
	Placebo (N=11)	Avapritinib 25 mg (N=25)	Placebo (N=56)	Avapritinib 25 mg (N=98)	
Gastrointestinal disorders, n (%)	1 (9.1)	6 (24.0)	13 (23.2)	21 (21.4)	0.303
Odds Ratio (95% CIs) [1], P-Value		3.158 (0.332, 29.998), 0.298		0.902 (0.411, 1.980), 0.797	
Relative Risk (95% CIs) [2], P-Value		2.640 (0.359, 19.404), 0.340		0.923 (0.502, 1.697), 0.797	
Risk Difference (95% CIs) [2], P-Value		0.149 (-0.089, 0.388), 0.221		-0.018 (-0.155, 0.119), 0.799	
Nausea, n (%)	1 (9.1)	5 (20.0)	9 (16.1)	13 (13.3)	0.363
Odds Ratio (95% CIs) [1], P-Value		2.500 (0.256, 24.375), 0.418		0.799 (0.318, 2.007), 0.632	
Relative Risk (95% CIs) [2], P-Value		2.200 (0.290, 16.693), 0.446		0.825 (0.377, 1.808), 0.631	
Risk Difference (95% CIs) [2], P-Value		0.109 (-0.122, 0.340), 0.355		-0.028 (-0.145, 0.089), 0.639	
Diarrhoea, n (%)	0	4 (16.0)	7 (12.5)	11 (11.2)	0.959
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.159		0.885 (0.322, 2.431), 0.813	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.898 (0.369, 2.184), 0.812	
Risk Difference (95% CIs) [2], P-Value		0.160 (0.016, 0.304), 0.029		-0.013 (-0.120, 0.094), 0.815	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.8a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=25)	No Placebo (N=56)	No Avapritinib 25 mg (N=98)	P-Value [3]
General disorders and administration site conditions, n (%)	0	4 (16.0)	8 (14.3)	17 (17.3)	0.955
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.159		1.259 (0.505, 3.138), 0.620	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.214 (0.560, 2.632), 0.623	
Risk Difference (95% CIs) [2], P-Value		0.160 (0.016, 0.304), 0.029		0.031 (-0.088, 0.149), 0.612	
Fatigue, n (%)	0	3 (12.0)	5 (8.9)	9 (9.2)	0.946
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.230		1.031 (0.328, 3.245), 0.958	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.029 (0.363, 2.918), 0.958	
Risk Difference (95% CIs) [2], P-Value		0.120 (-0.007, 0.247), 0.065		0.003 (-0.092, 0.097), 0.958	
Oedema peripheral, n (%)	0	2 (8.0)	3 (5.4)	9 (9.2)	0.954
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.334		1.787 (0.463, 6.893), 0.394	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.714 (0.484, 6.072), 0.404	
Risk Difference (95% CIs) [2], P-Value		0.080 (-0.026, 0.186), 0.140		0.038 (-0.044, 0.120), 0.361	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.8a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=25)	No Placebo (N=56)	No Avapritinib 25 mg (N=98)	P-Value [3]
Infections and infestations, n (%)	1 (9.1)	5 (20.0)	7 (12.5)	12 (12.2)	0.459
Odds Ratio (95% CIs) [1], P-Value		2.500 (0.256, 24.375), 0.418		0.977 (0.361, 2.644), 0.963	
Relative Risk (95% CIs) [2], P-Value		2.200 (0.290, 16.693), 0.446		0.980 (0.409, 2.344), 0.963	
Risk Difference (95% CIs) [2], P-Value		0.109 (-0.122, 0.340), 0.355		-0.003 (-0.111, 0.106), 0.963	
COVID-19, n (%)	1 (9.1)	5 (20.0)	7 (12.5)	12 (12.2)	0.459
Odds Ratio (95% CIs) [1], P-Value		2.500 (0.256, 24.375), 0.418		0.977 (0.361, 2.644), 0.963	
Relative Risk (95% CIs) [2], P-Value		2.200 (0.290, 16.693), 0.446		0.980 (0.409, 2.344), 0.963	
Risk Difference (95% CIs) [2], P-Value		0.109 (-0.122, 0.340), 0.355		-0.003 (-0.111, 0.106), 0.963	
Musculoskeletal and connective tissue disorders, n (%)	0	2 (8.0)	5 (8.9)	9 (9.2)	0.949
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.334		1.031 (0.328, 3.245), 0.958	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.029 (0.363, 2.918), 0.958	
Risk Difference (95% CIs) [2], P-Value		0.080 (-0.026, 0.186), 0.140		0.003 (-0.092, 0.097), 0.958	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.8a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=25)	No Placebo (N=56)	No Avapritinib 25 mg (N=98)	P-Value [3]
Musculoskeletal and connective tissue disorders (cont.)					
Arthralgia, n (%)	0	2 (8.0)	5 (8.9)	9 (9.2)	0.949
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.334		1.031 (0.328, 3.245), 0.958	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.029 (0.363, 2.918), 0.958	
Risk Difference (95% CIs) [2], P-Value		0.080 (-0.026, 0.186), 0.140		0.003 (-0.092, 0.097), 0.958	
Nervous system disorders, n (%)	1 (9.1)	5 (20.0)	16 (28.6)	28 (28.6)	0.453
Odds Ratio (95% CIs) [1], P-Value		2.500 (0.256, 24.375), 0.418		1.000 (0.483, 2.068), >0.999	
Relative Risk (95% CIs) [2], P-Value		2.200 (0.290, 16.693), 0.446		1.000 (0.595, 1.681), >0.999	
Risk Difference (95% CIs) [2], P-Value		0.109 (-0.122, 0.340), 0.355		0.000 (-0.148, 0.148), >0.999	
Headache, n (%)	0	3 (12.0)	14 (25.0)	21 (21.4)	0.951
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.230		0.818 (0.377, 1.774), 0.611	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.857 (0.475, 1.548), 0.609	
Risk Difference (95% CIs) [2], P-Value		0.120 (-0.007, 0.247), 0.065		-0.036 (-0.175, 0.104), 0.616	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.8a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Yes		No		P-Value [3]
	Placebo (N=11)	Avapritinib 25 mg (N=25)	Placebo (N=56)	Avapritinib 25 mg (N=98)	
Nervous system disorders (cont.)					
Dizziness, n (%)	1 (9.1)	2 (8.0)	5 (8.9)	12 (12.2)	0.725
Odds Ratio (95% CIs) [1], P-Value		0.870 (0.070, 10.728), 0.913		1.423 (0.474, 4.273), 0.528	
Relative Risk (95% CIs) [2], P-Value		0.880 (0.089, 8.719), 0.913		1.371 (0.509, 3.692), 0.532	
Risk Difference (95% CIs) [2], P-Value		-0.011 (-0.211, 0.190), 0.915		0.033 (-0.066, 0.132), 0.511	
Skin and subcutaneous tissue disorders, n (%)	0	2 (8.0)	5 (8.9)	8 (8.2)	0.950
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.334		0.907 (0.282, 2.918), 0.869	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.914 (0.314, 2.660), 0.869	
Risk Difference (95% CIs) [2], P-Value		0.080 (-0.026, 0.186), 0.140		-0.008 (-0.100, 0.085), 0.871	
Pruritus, n (%)	0	2 (8.0)	5 (8.9)	8 (8.2)	0.950
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.334		0.907 (0.282, 2.918), 0.869	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.914 (0.314, 2.660), 0.869	
Risk Difference (95% CIs) [2], P-Value		0.080 (-0.026, 0.186), 0.140		-0.008 (-0.100, 0.085), 0.871	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.2.1.1.1.2.8a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=25)	No Placebo (N=56)	No Avapritinib 25 mg (N=98)	P-Value [3]
Vascular disorders, n (%)	0	5 (20.0)	2 (3.6)	6 (6.1)	0.951
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.110		1.761 (0.343, 9.034), 0.493	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.714 (0.358, 8.209), 0.500	
Risk Difference (95% CIs) [2], P-Value		0.200 (0.043, 0.357), 0.012		0.026 (-0.042, 0.093), 0.462	
Flushing, n (%)	0	5 (20.0)	2 (3.6)	6 (6.1)	0.951
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.110		1.761 (0.343, 9.034), 0.493	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.714 (0.358, 8.209), 0.500	
Risk Difference (95% CIs) [2], P-Value		0.200 (0.043, 0.357), 0.012		0.026 (-0.042, 0.093), 0.462	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.3.1.2.1a
Summary of Serious Adverse Events Occurred >= 5 % in at Least One Treatment Group by System Organ Class and Preferred Term by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Protocol: BLU-285-2203
CSR Germany

Table 35.3.1.3.1.2.2a
Summary of Serious Adverse Events Occurred >= 5 % in at Least One Treatment Group by System Organ Class and Preferred Term by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

Table 35.3.1.3.1.2.3a
Summary of Serious Adverse Events Occurred >= 5 % in at Least One Treatment Group by System Organ Class and Preferred Term by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.3.1.2.9a
Summary of Serious Adverse Events Occurred >= 5 % in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sae-socpt-ge5p-pp-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.3.1.2.4a
Summary of Serious Adverse Events Occurred >= 5 % in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sae-socpt-ge5p-pp-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.3.1.2.5a
Summary of Serious Adverse Events Occurred >= 5 % in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sae-socpt-ge5p-pp-subgrp-a.sas Date: 17:19/05MAY2023

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Table 35.3.1.3.1.2.6a
Summary of Serious Adverse Events Occurred >= 5 % in at Least One Treatment Group by System Organ Class and Preferred Term
by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sae-socpt-ge5p-pp-subgrp-a.sas Date: 17:19/05MAY2023

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Table 35.3.1.3.1.2.7a
Summary of Serious Adverse Events Occurred >= 5 % in at Least One Treatment Group by System Organ Class and Preferred Term by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sae-socpt-ge5p-pp-subgrp-a.sas Date: 17:19/05MAY2023

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Table 35.3.1.3.1.2.8a
Summary of Serious Adverse Events Occurred >= 5 % in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sae-socpt-ge5p-pp-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.4.1.2.1a
Summary of Grade 3 or Higher Adverse Events Occurred >= 5 % in at Least One Treatment Group by System Organ Class and Preferred Term by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-grd3-ge5p-pp-subgrp-a.sas Date: 17:17/05MAY2023

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Table 35.3.1.4.1.2.2a
Summary of Grade 3 or Higher Adverse Events Occurred >= 5 % in at Least One Treatment Group by System Organ Class and Preferred Term by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-grd3-ge5p-pp-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.4.1.2.3a
Summary of Grade 3 or Higher Adverse Events Occurred >= 5 % in at Least One Treatment Group by System Organ Class and Preferred Term by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-grd3-ge5p-pp-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.4.1.2.9a
Summary of Grade 3 or Higher Adverse Events Occurred >= 5 % in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-grd3-ge5p-pp-cntry-a.sas Date: 11:52/20JUL2023

Table 35.3.1.4.1.2.4a
Summary of Grade 3 or Higher Adverse Events Occurred >= 5 % in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-grd3-ge5p-pp-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.4.1.2.5a
Summary of Grade 3 or Higher Adverse Events Occurred >= 5 % in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-grd3-ge5p-pp-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.4.1.2.6a
Summary of Grade 3 or Higher Adverse Events Occurred >= 5 % in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-grd3-ge5p-pp-subgrp-a.sas Date: 17:17/05MAY2023

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Table 35.3.1.4.1.2.7a
Summary of Grade 3 or Higher Adverse Events Occurred >= 5 % in at Least One Treatment Group by System Organ Class and Preferred Term by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-grd3-ge5p-pp-subgrp-a.sas Date: 17:17/05MAY2023

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Table 35.3.1.4.1.2.8a
Summary of Grade 3 or Higher Adverse Events Occurred >= 5 % in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-grd3-ge5p-pp-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.11.1.2.1a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=56)	<65 Years Avapritinib 25 mg (N=117)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=6)	P-Value [3]
Patients with at least one AESI, n (%)	2 (3.6)	4 (3.4)	1 (9.1)	0	0.959
Odds Ratio (95% CIs) [1], P-Value		0.956 (0.170, 5.381), 0.959		NE (NE, NE), 0.446	
Relative Risk (95% CIs) [2], P-Value		0.957 (0.181, 5.071), 0.959		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.002 (-0.060, 0.057), 0.959		-0.091 (-0.261, 0.079), 0.294	
Cognitive Effects, n (%)	2 (3.6)	4 (3.4)	1 (9.1)	0	0.959
Odds Ratio (95% CIs) [1], P-Value		0.956 (0.170, 5.381), 0.959		NE (NE, NE), 0.446	
Relative Risk (95% CIs) [2], P-Value		0.957 (0.181, 5.071), 0.959		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.002 (-0.060, 0.057), 0.959		-0.091 (-0.261, 0.079), 0.294	
Memory impairment, n (%)	1 (1.8)	2 (1.7)	0	0	>0.999
Odds Ratio (95% CIs) [1], P-Value		0.957 (0.085, 10.777), 0.971		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		0.957 (0.089, 10.335), 0.971		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.001 (-0.043, 0.041), 0.972		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-pp-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.2.1a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=56)	<65 Years Avapritinib 25 mg (N=117)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=6)	P-Value [3]
Cognitive Effects (cont.)					
Amnesia, n (%)	0	1 (0.9)	0	0	0.983
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.488		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.009 (-0.008, 0.025), 0.315		NA (NA, NA), NA	
Mood altered, n (%)	0	1 (0.9)	0	0	0.983
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.488		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.009 (-0.008, 0.025), 0.315		NA (NA, NA), NA	
Mental impairment, n (%)	1 (1.8)	0	0	0	0.982
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.147		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.018 (-0.053, 0.017), 0.313		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-pp-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.2.1a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=56)	<65 Years Avapritinib 25 mg (N=117)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=6)	P-Value [3]
Cognitive Effects (cont.)					
Mental status changes, n (%)	0	0	1 (9.1)	0	0.967
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.446	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.091 (-0.261, 0.079), 0.294	
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-pp-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.2.1a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=56)	<65 Years Avapritinib 25 mg (N=117)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=6)	P-Value [3]
Cognitive Effects (cont.)					
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.1a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=56)	<65 Years Avapritinib 25 mg (N=117)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=6)	P-Value [3]
Cognitive Effects (cont.)					
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.1a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=56)	<65 Years Avapritinib 25 mg (N=117)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=6)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.1a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=56)	<65 Years Avapritinib 25 mg (N=117)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=6)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.1a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=56)	<65 Years Avapritinib 25 mg (N=117)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=6)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.2a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=15)	Male Avapritinib 25 mg (N=35)	Female Placebo (N=52)	Female Avapritinib 25 mg (N=88)	P-Value [3]
Patients with at least one AESI, n (%)	1 (6.7)	1 (2.9)	2 (3.8)	3 (3.4)	0.658
Odds Ratio (95% CIs) [1], P-Value		0.412 (0.024, 7.053), 0.529		0.882 (0.143, 5.462), 0.893	
Relative Risk (95% CIs) [2], P-Value		0.429 (0.029, 6.409), 0.539		0.886 (0.153, 5.132), 0.893	
Risk Difference (95% CIs) [2], P-Value		-0.038 (-0.176, 0.100), 0.588		-0.004 (-0.069, 0.060), 0.894	
Cognitive Effects, n (%)	1 (6.7)	1 (2.9)	2 (3.8)	3 (3.4)	0.658
Odds Ratio (95% CIs) [1], P-Value		0.412 (0.024, 7.053), 0.529		0.882 (0.143, 5.462), 0.893	
Relative Risk (95% CIs) [2], P-Value		0.429 (0.029, 6.409), 0.539		0.886 (0.153, 5.132), 0.893	
Risk Difference (95% CIs) [2], P-Value		-0.038 (-0.176, 0.100), 0.588		-0.004 (-0.069, 0.060), 0.894	
Memory impairment, n (%)	1 (6.7)	1 (2.9)	0	1 (1.1)	0.947
Odds Ratio (95% CIs) [1], P-Value		0.412 (0.024, 7.053), 0.529		NE (NE, NE), 0.440	
Relative Risk (95% CIs) [2], P-Value		0.429 (0.029, 6.409), 0.539		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.038 (-0.176, 0.100), 0.588		0.011 (-0.011, 0.034), 0.315	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.2a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=15)	Male Avapritinib 25 mg (N=35)	Female Placebo (N=52)	Female Avapritinib 25 mg (N=88)	P-Value [3]
Cognitive Effects (cont.)					
Amnesia, n (%)	0	0	0	1 (1.1)	0.973
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.440	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.011 (-0.011, 0.034), 0.315	
Mood altered, n (%)	0	0	0	1 (1.1)	0.973
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.440	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.011 (-0.011, 0.034), 0.315	
Mental impairment, n (%)	0	0	1 (1.9)	0	0.967
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.192	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.019 (-0.057, 0.018), 0.313	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-pp-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.2.2a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=15)	Male Avapritinib 25 mg (N=35)	Female Placebo (N=52)	Female Avapritinib 25 mg (N=88)	P-Value [3]
Cognitive Effects (cont.)					
Mental status changes, n (%)	0	0	1 (1.9)	0	0.967
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.192	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.019 (-0.057, 0.018), 0.313	
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-pp-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.2.2a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=15)	Male Avapritinib 25 mg (N=35)	Female Placebo (N=52)	Female Avapritinib 25 mg (N=88)	P-Value [3]
Cognitive Effects (cont.)					
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.2a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=15)	Male Avapritinib 25 mg (N=35)	Female Placebo (N=52)	Female Avapritinib 25 mg (N=88)	P-Value [3]
Cognitive Effects (cont.)					
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.2a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=15)	Male Avapritinib 25 mg (N=35)	Female Placebo (N=52)	Female Avapritinib 25 mg (N=88)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.2a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=15)	Male Avapritinib 25 mg (N=35)	Female Placebo (N=52)	Female Avapritinib 25 mg (N=88)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.2a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=15)	Male Avapritinib 25 mg (N=35)	Female Placebo (N=52)	Female Avapritinib 25 mg (N=88)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Protocol: BLU-285-2203
CSR Germany

Table 35.3.1.11.1.2.3a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=32)	North America Avapritinib 25 mg (N=52)	Europe Placebo (N=35)	Europe Avapritinib 25 mg (N=71)	P-Value [3]
Patients with at least one AESI, n (%)	2 (6.3)	2 (3.8)	1 (2.9)	2 (2.8)	0.758
Odds Ratio (95% CIs) [1], P-Value		0.600 (0.080, 4.485), 0.615		0.986 (0.086, 11.254), 0.991	
Relative Risk (95% CIs) [2], P-Value		0.615 (0.091, 4.155), 0.618		0.986 (0.093, 10.505), 0.991	
Risk Difference (95% CIs) [2], P-Value		-0.024 (-0.123, 0.075), 0.634		-0.000 (-0.068, 0.067), 0.991	
Cognitive Effects, n (%)	2 (6.3)	2 (3.8)	1 (2.9)	2 (2.8)	0.758
Odds Ratio (95% CIs) [1], P-Value		0.600 (0.080, 4.485), 0.615		0.986 (0.086, 11.254), 0.991	
Relative Risk (95% CIs) [2], P-Value		0.615 (0.091, 4.155), 0.618		0.986 (0.093, 10.505), 0.991	
Risk Difference (95% CIs) [2], P-Value		-0.024 (-0.123, 0.075), 0.634		-0.000 (-0.068, 0.067), 0.991	
Memory impairment, n (%)	1 (3.1)	2 (3.8)	0	0	0.999
Odds Ratio (95% CIs) [1], P-Value		1.240 (0.108, 14.254), 0.863		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		1.231 (0.116, 13.031), 0.863		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.007 (-0.073, 0.087), 0.859		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.3a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=32)	North America Avapritinib 25 mg (N=52)	Europe Placebo (N=35)	Europe Avapritinib 25 mg (N=71)	P-Value [3]
Cognitive Effects (cont.)					
Amnesia, n (%)	0	0	0	1 (1.4)	0.966
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.481	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.014 (-0.013, 0.041), 0.314	
Mood altered, n (%)	0	0	0	1 (1.4)	0.966
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.481	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.014 (-0.013, 0.041), 0.314	
Mental impairment, n (%)	0	0	1 (2.9)	0	0.957
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.152	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.029 (-0.084, 0.027), 0.310	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.3a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=32)	North America Avapritinib 25 mg (N=52)	Europe Placebo (N=35)	Europe Avapritinib 25 mg (N=71)	P-Value [3]
Cognitive Effects (cont.)					
Mental status changes, n (%)	1 (3.1)	0	0	0	0.970
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.200		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.031 (-0.092, 0.029), 0.310		NA (NA, NA), NA	
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.11.1.2.3a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=32)	North America Avapritinib 25 mg (N=52)	Europe Placebo (N=35)	Europe Avapritinib 25 mg (N=71)	P-Value [3]
Cognitive Effects (cont.)					
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.11.1.2.3a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=32)	North America Avapritinib 25 mg (N=52)	Europe Placebo (N=35)	Europe Avapritinib 25 mg (N=71)	P-Value [3]
Cognitive Effects (cont.)					
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.11.1.2.3a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=32)	North America Avapritinib 25 mg (N=52)	Europe Placebo (N=35)	Europe Avapritinib 25 mg (N=71)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
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by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=32)	North America Avapritinib 25 mg (N=52)	Europe Placebo (N=35)	Europe Avapritinib 25 mg (N=71)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.11.1.2.3a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=32)	North America Avapritinib 25 mg (N=52)	Europe Placebo (N=35)	Europe Avapritinib 25 mg (N=71)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=27)	United States Avapritinib 25 mg (N=44)	Germany Placebo (N=14)	Germany Avapritinib 25 mg (N=17)
Cognitive Effects, n (%)	2 (7.4)	2 (4.5)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Memory impairment, n (%)	1 (3.7)	2 (4.5)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Amnesia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mood altered, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

	Spain		France	
System Organ Class Preferred Term	Placebo (N=3)	Avapritinib 25 mg (N=13)	Placebo (N=5)	Avapritinib 25 mg (N=10)
Cognitive Effects, n (%)	0	1 (7.7)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Memory impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Amnesia, n (%)	0	1 (7.7)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mood altered, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=10)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Cognitive Effects, n (%)	1 (20.0)	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Memory impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Amnesia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mood altered, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=7)	Norway Placebo (N=2)	Norway Avapritinib 25 mg (N=5)
Cognitive Effects, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Memory impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Amnesia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mood altered, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=2)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=3)
Cognitive Effects, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Memory impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Amnesia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mood altered, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Switzerland Placebo (N=1)	Switzerland Avapritinib 25 mg (N=2)	Sweden Placebo (N=1)	Sweden Avapritinib 25 mg (N=1)
Cognitive Effects, n (%)	0	1 (50.0)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Memory impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Amnesia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mood altered, n (%)	0	1 (50.0)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Cognitive Effects, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Memory impairment, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Amnesia, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Mood altered, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=27)	United States Avapritinib 25 mg (N=44)	Germany Placebo (N=14)	Germany Avapritinib 25 mg (N=17)
Cognitive Effects (cont.)	0	0	0	0
Mental impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mental status changes, n (%)	1 (3.7)	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Agitation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cognitive disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=13)	France Placebo (N=5)	France Avapritinib 25 mg (N=10)
Cognitive Effects (cont.)	0	0	0	0
Mental impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mental status changes, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Agitation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cognitive disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=10)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Cognitive Effects (cont.)	1 (20.0)	0	0	0
Mental impairment, n (%)	1 (20.0)	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mental status changes, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Agitation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cognitive disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=7)	Norway Placebo (N=2)	Norway Avapritinib 25 mg (N=5)
Cognitive Effects (cont.)	0	0	0	0
Mental impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mental status changes, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Agitation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cognitive disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=2)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=3)
Cognitive Effects (cont.)	0	0	0	0
Mental impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mental status changes, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Agitation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cognitive disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Switzerland Placebo (N=1)	Switzerland Avapritinib 25 mg (N=2)	Sweden Placebo (N=1)	Sweden Avapritinib 25 mg (N=1)
Cognitive Effects (cont.)	0	0	0	0
Mental impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mental status changes, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Agitation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cognitive disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Cognitive Effects (cont.)	0	0	-
Mental impairment, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Mental status changes, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Agitation, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=27)	United States Avapritinib 25 mg (N=44)	Germany Placebo (N=14)	Germany Avapritinib 25 mg (N=17)
Cognitive Effects (cont.)	0	0	0	0
Confusional state, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Delirium, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dementia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Disorientation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=13)	France Placebo (N=5)	France Avapritinib 25 mg (N=10)
Cognitive Effects (cont.)	0	0	0	0
Confusional state, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Delirium, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dementia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Disorientation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=10)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Cognitive Effects (cont.)	0	0	0	0
Confusional state, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Delirium, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dementia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Disorientation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=7)	Norway Placebo (N=2)	Norway Avapritinib 25 mg (N=5)
Cognitive Effects (cont.)	0	0	0	0
Confusional state, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Delirium, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dementia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Disorientation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=2)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=3)
Cognitive Effects (cont.)	0	0	0	0
Confusional state, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Delirium, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dementia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Disorientation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Switzerland Placebo (N=1)	Switzerland Avapritinib 25 mg (N=2)	Sweden Placebo (N=1)	Sweden Avapritinib 25 mg (N=1)
Cognitive Effects (cont.)	0	0	0	0
Confusional state, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Delirium, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dementia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Disorientation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Cognitive Effects (cont.)	0	0	-
Confusional state, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Delirium, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Dementia, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Disorientation, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=27)	United States Avapritinib 25 mg (N=44)	Germany Placebo (N=14)	Germany Avapritinib 25 mg (N=17)
Cognitive Effects (cont.)	0	0	0	0
Encephalopathy, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hallucination, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Personality change, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Psychotic disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=13)	France Placebo (N=5)	France Avapritinib 25 mg (N=10)
Cognitive Effects (cont.)	0	0	0	0
Encephalopathy, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hallucination, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Personality change, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Psychotic disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=10)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Cognitive Effects (cont.)	0	0	0	0
Encephalopathy, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hallucination, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Personality change, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Psychotic disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=7)	Norway Placebo (N=2)	Norway Avapritinib 25 mg (N=5)
Cognitive Effects (cont.)	0	0	0	0
Encephalopathy, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hallucination, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Personality change, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Psychotic disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=2)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=3)
Cognitive Effects (cont.)	0	0	0	0
Encephalopathy, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hallucination, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Personality change, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Psychotic disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Switzerland Placebo (N=1)	Switzerland Avapritinib 25 mg (N=2)	Sweden Placebo (N=1)	Sweden Avapritinib 25 mg (N=1)
Cognitive Effects (cont.)	0	0	0	0
Encephalopathy, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hallucination, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Personality change, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Psychotic disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Cognitive Effects (cont.)	0	0	-
Encephalopathy, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Hallucination, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Personality change, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=27)	United States Avapritinib 25 mg (N=44)	Germany Placebo (N=14)	Germany Avapritinib 25 mg (N=17)
Cognitive Effects (cont.)	0	0	0	0
Somnolence, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Speech disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Intracranial Bleeding, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cerebral haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=13)	France Placebo (N=5)	France Avapritinib 25 mg (N=10)
Cognitive Effects (cont.)	0	0	0	0
Somnolence, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Speech disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Intracranial Bleeding, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cerebral haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=10)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Cognitive Effects (cont.)	0	0	0	0
Somnolence, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Speech disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Intracranial Bleeding, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cerebral haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=7)	Norway Placebo (N=2)	Norway Avapritinib 25 mg (N=5)
Cognitive Effects (cont.)	0	0	0	0
Somnolence, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Speech disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Intracranial Bleeding, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cerebral haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=2)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=3)
Cognitive Effects (cont.)	0	0	0	0
Somnolence, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Speech disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Intracranial Bleeding, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cerebral haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Switzerland Placebo (N=1)	Switzerland Avapritinib 25 mg (N=2)	Sweden Placebo (N=1)	Sweden Avapritinib 25 mg (N=1)
Cognitive Effects (cont.)	0	0	0	0
Somnolence, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Speech disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Intracranial Bleeding, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cerebral haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Cognitive Effects (cont.)	0	0	-
Somnolence, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Speech disorder, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=27)	United States Avapritinib 25 mg (N=44)	Germany Placebo (N=14)	Germany Avapritinib 25 mg (N=17)
Intracranial Bleeding (cont.)	0	0	0	0
Cerebral haemorrhage, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Haemorrhage intracranial, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Subdural haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Spain		France	
	Placebo (N=3)	Avapritinib 25 mg (N=13)	Placebo (N=5)	Avapritinib 25 mg (N=10)
Intracranial Bleeding (cont.)	0	0	0	0
Cerebral haemorrhage, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Haemorrhage intracranial, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Subdural haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=10)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Intracranial Bleeding (cont.)	0	0	0	0
Cerebral haemorrhage, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Haemorrhage intracranial, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Subdural haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=7)	Norway Placebo (N=2)	Norway Avapritinib 25 mg (N=5)
Intracranial Bleeding (cont.)	0	0	0	0
Cerebral haemorrhage, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Haemorrhage intracranial, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Subdural haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=2)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=3)
Intracranial Bleeding (cont.)	0	0	0	0
Cerebral haemorrhage, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Haemorrhage intracranial, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Subdural haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Switzerland		Sweden	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=1)	Avapritinib 25 mg (N=1)
Intracranial Bleeding (cont.)	0	0	0	0
Cerebral haemorrhage, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Haemorrhage intracranial, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Subdural haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Intracranial Bleeding (cont.)	0	0	-
Cerebral haemorrhage, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.4a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=22)	Moderate Avapritinib 25 mg (N=37)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=86)	P-Value [3]
Patients with at least one AESI, n (%)	2 (9.1)	1 (2.7)	1 (2.2)	3 (3.5)	0.309
Odds Ratio (95% CIs) [1], P-Value		0.278 (0.024, 3.258), 0.280		1.590 (0.161, 15.744), 0.689	
Relative Risk (95% CIs) [2], P-Value		0.297 (0.029, 3.092), 0.310		1.570 (0.168, 14.661), 0.692	
Risk Difference (95% CIs) [2], P-Value		-0.064 (-0.195, 0.067), 0.339		0.013 (-0.045, 0.071), 0.669	
Cognitive Effects, n (%)	2 (9.1)	1 (2.7)	1 (2.2)	3 (3.5)	0.309
Odds Ratio (95% CIs) [1], P-Value		0.278 (0.024, 3.258), 0.280		1.590 (0.161, 15.744), 0.689	
Relative Risk (95% CIs) [2], P-Value		0.297 (0.029, 3.092), 0.310		1.570 (0.168, 14.661), 0.692	
Risk Difference (95% CIs) [2], P-Value		-0.064 (-0.195, 0.067), 0.339		0.013 (-0.045, 0.071), 0.669	
Memory impairment, n (%)	1 (4.5)	1 (2.7)	0	1 (1.2)	0.954
Odds Ratio (95% CIs) [1], P-Value		0.583 (0.035, 9.822), 0.705		NE (NE, NE), 0.468	
Relative Risk (95% CIs) [2], P-Value		0.595 (0.039, 9.036), 0.708		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.018 (-0.120, 0.083), 0.722		0.012 (-0.011, 0.034), 0.314	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.4a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=22)	Moderate Avapritinib 25 mg (N=37)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=86)	P-Value [3]
Cognitive Effects (cont.)					
Amnesia, n (%)	0	0	0	1 (1.2)	0.970
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.468	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.012 (-0.011, 0.034), 0.314	
Mood altered, n (%)	0	0	0	1 (1.2)	0.970
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.468	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.012 (-0.011, 0.034), 0.314	
Mental impairment, n (%)	0	0	1 (2.2)	0	0.965
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.165	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.022 (-0.065, 0.021), 0.312	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.4a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=22)	Moderate Avapritinib 25 mg (N=37)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=86)	P-Value [3]
Cognitive Effects (cont.)					
Mental status changes, n (%)	1 (4.5)	0	0	0	0.964
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.191		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.045 (-0.132, 0.042), 0.306		NA (NA, NA), NA	
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.4a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=22)	Moderate Avapritinib 25 mg (N=37)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=86)	P-Value [3]
Cognitive Effects (cont.)					
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.4a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=22)	Moderate Avapritinib 25 mg (N=37)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=86)	P-Value [3]
Cognitive Effects (cont.)					
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.4a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=22)	Moderate Avapritinib 25 mg (N=37)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=86)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.4a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=22)	Moderate Avapritinib 25 mg (N=37)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=86)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.4a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=22)	Moderate Avapritinib 25 mg (N=37)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=86)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.5a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=13)	<20 ng/mL Avapritinib 25 mg (N=26)	>=20 ng/mL Placebo (N=54)	>=20 ng/mL Avapritinib 25 mg (N=97)	P-Value [3]
Patients with at least one AESI, n (%)	1 (7.7)	0	2 (3.7)	4 (4.1)	0.962
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.152		1.118 (0.198, 6.314), 0.899	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.113 (0.211, 5.882), 0.899	
Risk Difference (95% CIs) [2], P-Value		-0.077 (-0.222, 0.068), 0.298		0.004 (-0.060, 0.068), 0.898	
Cognitive Effects, n (%)	1 (7.7)	0	2 (3.7)	4 (4.1)	0.962
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.152		1.118 (0.198, 6.314), 0.899	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.113 (0.211, 5.882), 0.899	
Risk Difference (95% CIs) [2], P-Value		-0.077 (-0.222, 0.068), 0.298		0.004 (-0.060, 0.068), 0.898	
Memory impairment, n (%)	1 (7.7)	0	0	2 (2.1)	0.927
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.152		NE (NE, NE), 0.288	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.077 (-0.222, 0.068), 0.298		0.021 (-0.008, 0.049), 0.153	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.5a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=13)	<20 ng/mL Avapritinib 25 mg (N=26)	>=20 ng/mL Placebo (N=54)	>=20 ng/mL Avapritinib 25 mg (N=97)	P-Value [3]
Cognitive Effects (cont.)					
Amnesia, n (%)	0	0	0	1 (1.0)	0.975
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.454	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.010 (-0.010, 0.030), 0.315	
Mood altered, n (%)	0	0	0	1 (1.0)	0.975
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.454	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.010 (-0.010, 0.030), 0.315	
Mental impairment, n (%)	0	0	1 (1.9)	0	0.972
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.179	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.019 (-0.054, 0.017), 0.313	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.5a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=13)	<20 ng/mL Avapritinib 25 mg (N=26)	>=20 ng/mL Placebo (N=54)	>=20 ng/mL Avapritinib 25 mg (N=97)	P-Value [3]
Cognitive Effects (cont.)					
Mental status changes, n (%)	0	0	1 (1.9)	0	0.972
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.179	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.019 (-0.054, 0.017), 0.313	
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.5a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=13)	<20 ng/mL Avapritinib 25 mg (N=26)	>=20 ng/mL Placebo (N=54)	>=20 ng/mL Avapritinib 25 mg (N=97)	P-Value [3]
Cognitive Effects (cont.)					
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.5a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=13)	<20 ng/mL Avapritinib 25 mg (N=26)	>=20 ng/mL Placebo (N=54)	>=20 ng/mL Avapritinib 25 mg (N=97)	P-Value [3]
Cognitive Effects (cont.)					
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.5a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=13)	<20 ng/mL Avapritinib 25 mg (N=26)	>=20 ng/mL Placebo (N=54)	>=20 ng/mL Avapritinib 25 mg (N=97)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.5a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=13)	<20 ng/mL Avapritinib 25 mg (N=26)	>=20 ng/mL Placebo (N=54)	>=20 ng/mL Avapritinib 25 mg (N=97)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.5a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=13)	<20 ng/mL Avapritinib 25 mg (N=26)	>=20 ng/mL Placebo (N=54)	>=20 ng/mL Avapritinib 25 mg (N=97)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.6a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=32)	 Avapritinib 25 mg (N=63)	Number of Baseline BSC >=4 Placebo (N=35)	 Avapritinib 25 mg (N=60)	P-Value [3]
Patients with at least one AESI, n (%)	0	0	3 (8.6)	4 (6.7)	0.999
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.762 (0.160, 3.621), 0.732	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.778 (0.185, 3.275), 0.732	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.019 (-0.131, 0.093), 0.739	
Cognitive Effects, n (%)	0	0	3 (8.6)	4 (6.7)	0.999
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.762 (0.160, 3.621), 0.732	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.778 (0.185, 3.275), 0.732	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.019 (-0.131, 0.093), 0.739	
Memory impairment, n (%)	0	0	1 (2.9)	2 (3.3)	>0.999
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		1.172 (0.102, 13.418), 0.898	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		1.167 (0.110, 12.405), 0.898	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.005 (-0.067, 0.076), 0.896	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.6a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=32)	 Avapritinib 25 mg (N=63)	Number of Baseline BSC >=4 Placebo (N=35)	 Avapritinib 25 mg (N=60)	P-Value [3]
Cognitive Effects (cont.)					
Amnesia, n (%)	0	0	0	1 (1.7)	0.965
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.443	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.017 (-0.016, 0.049), 0.313	
Mood altered, n (%)	0	0	0	1 (1.7)	0.965
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.443	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.017 (-0.016, 0.049), 0.313	
Mental impairment, n (%)	0	0	1 (2.9)	0	0.957
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.188	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.029 (-0.084, 0.027), 0.310	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.11.1.2.6a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=32)	 Avapritinib 25 mg (N=63)	Number of Baseline BSC >=4 Placebo (N=35)	 Avapritinib 25 mg (N=60)	P-Value [3]
Cognitive Effects (cont.)					
Mental status changes, n (%)	0	0	1 (2.9)	0	0.957
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.188	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.029 (-0.084, 0.027), 0.310	
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.11.1.2.6a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=32)	 Avapritinib 25 mg (N=63)	Number of Baseline BSC >=4 Placebo (N=35)	 Avapritinib 25 mg (N=60)	P-Value [3]
Cognitive Effects (cont.)					
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.11.1.2.6a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=32)	 Avapritinib 25 mg (N=63)	Number of Baseline BSC >=4 Placebo (N=35)	 Avapritinib 25 mg (N=60)	P-Value [3]
Cognitive Effects (cont.)					
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.6a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=32)	 Avapritinib 25 mg (N=63)	Number of Baseline BSC >=4 Placebo (N=35)	 Avapritinib 25 mg (N=60)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.11.1.2.6a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=32)	 Avapritinib 25 mg (N=63)	Number of Baseline BSC >=4 Placebo (N=35)	 Avapritinib 25 mg (N=60)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.6a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=32)	 Avapritinib 25 mg (N=63)	Number of Baseline BSC >=4 Placebo (N=35)	 Avapritinib 25 mg (N=60)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.7a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=6)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=61)	No Avapritinib 25 mg (N=104)	P-Value [3]
Patients with at least one AESI, n (%)	0	1 (5.3)	3 (4.9)	3 (2.9)	0.959
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.566		0.574 (0.112, 2.938), 0.501	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.587 (0.122, 2.816), 0.505	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		-0.020 (-0.083, 0.043), 0.528	
Cognitive Effects, n (%)	0	1 (5.3)	3 (4.9)	3 (2.9)	0.959
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.566		0.574 (0.112, 2.938), 0.501	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.587 (0.122, 2.816), 0.505	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		-0.020 (-0.083, 0.043), 0.528	
Memory impairment, n (%)	0	0	1 (1.6)	2 (1.9)	>0.999
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		1.176 (0.104, 13.251), 0.895	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		1.173 (0.109, 12.669), 0.895	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.003 (-0.039, 0.044), 0.893	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.7a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes		No		P-Value [3]
	Placebo (N=6)	Avapritinib 25 mg (N=19)	Placebo (N=61)	Avapritinib 25 mg (N=104)	
Cognitive Effects (cont.)					
Amnesia, n (%)	0	0	0	1 (1.0)	0.981
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.442	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.010 (-0.009, 0.028), 0.315	
Mood altered, n (%)	0	1 (5.3)	0	0	0.960
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.566		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		NA (NA, NA), NA	
Mental impairment, n (%)	0	0	1 (1.6)	0	0.980
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.190	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.016 (-0.048, 0.015), 0.313	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Summary of Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=6)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=61)	No Avapritinib 25 mg (N=104)	P-Value [3]
Cognitive Effects (cont.)					
Mental status changes, n (%)	0	0	1 (1.6)	0	0.980
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.190	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.016 (-0.048, 0.015), 0.313	
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.7a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=6)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=61)	No Avapritinib 25 mg (N=104)	P-Value [3]
Cognitive Effects (cont.)					
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.7a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=6)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=61)	No Avapritinib 25 mg (N=104)	P-Value [3]
Cognitive Effects (cont.)					
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.7a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=6)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=61)	No Avapritinib 25 mg (N=104)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.7a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=6)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=61)	No Avapritinib 25 mg (N=104)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.7a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes		No		P-Value [3]
	Placebo (N=6)	Avapritinib 25 mg (N=19)	Placebo (N=61)	Avapritinib 25 mg (N=104)	
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.8a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=25)	No Placebo (N=56)	No Avapritinib 25 mg (N=98)	P-Value [3]
Patients with at least one AESI, n (%)	0	1 (4.0)	3 (5.4)	3 (3.1)	0.946
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.501		0.558 (0.109, 2.862), 0.479	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.571 (0.119, 2.736), 0.484	
Risk Difference (95% CIs) [2], P-Value		0.040 (-0.037, 0.117), 0.307		-0.023 (-0.091, 0.045), 0.509	
Cognitive Effects, n (%)	0	1 (4.0)	3 (5.4)	3 (3.1)	0.946
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.501		0.558 (0.109, 2.862), 0.479	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.571 (0.119, 2.736), 0.484	
Risk Difference (95% CIs) [2], P-Value		0.040 (-0.037, 0.117), 0.307		-0.023 (-0.091, 0.045), 0.509	
Memory impairment, n (%)	0	0	1 (1.8)	2 (2.0)	>0.999
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		1.146 (0.102, 12.928), 0.912	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		1.143 (0.106, 12.323), 0.912	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.003 (-0.042, 0.047), 0.911	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.8a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=25)	No Placebo (N=56)	No Avapritinib 25 mg (N=98)	P-Value [3]
Cognitive Effects (cont.)					
Amnesia, n (%)	0	0	0	1 (1.0)	0.976
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.448	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.010 (-0.010, 0.030), 0.315	
Mood altered, n (%)	0	1 (4.0)	0	0	0.955
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.501		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.040 (-0.037, 0.117), 0.307		NA (NA, NA), NA	
Mental impairment, n (%)	0	0	1 (1.8)	0	0.973
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.184	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.018 (-0.053, 0.017), 0.313	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.8a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=25)	No Placebo (N=56)	No Avapritinib 25 mg (N=98)	P-Value [3]
Cognitive Effects (cont.)					
Mental status changes, n (%)	0	0	1 (1.8)	0	0.973
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.184	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.018 (-0.053, 0.017), 0.313	
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.8a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=25)	No Placebo (N=56)	No Avapritinib 25 mg (N=98)	P-Value [3]
Cognitive Effects (cont.)					
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.8a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=25)	No Placebo (N=56)	No Avapritinib 25 mg (N=98)	P-Value [3]
Cognitive Effects (cont.)					
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.8a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=25)	No Placebo (N=56)	No Avapritinib 25 mg (N=98)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.8a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=25)	No Placebo (N=56)	No Avapritinib 25 mg (N=98)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.1.2.8a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=25)	No Placebo (N=56)	No Avapritinib 25 mg (N=98)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.1a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=56)	<65 Years Avapritinib 25 mg (N=117)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=6)	P-Value [3]
Patients with at least one Serious AESI, n (%)	0	0	1 (9.1)	0	0.967
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.446	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.091 (-0.261, 0.079), 0.294	
Cognitive Effects, n (%)	0	0	1 (9.1)	0	0.967
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.446	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.091 (-0.261, 0.079), 0.294	
Mental status changes, n (%)	0	0	1 (9.1)	0	0.967
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.446	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.091 (-0.261, 0.079), 0.294	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.1a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=56)	<65 Years Avapritinib 25 mg (N=117)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=6)	P-Value [3]
Cognitive Effects (cont.)					
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Amnesia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.1a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=56)	<65 Years Avapritinib 25 mg (N=117)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=6)	P-Value [3]
Cognitive Effects (cont.)					
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.1a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=56)	<65 Years Avapritinib 25 mg (N=117)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=6)	P-Value [3]
Cognitive Effects (cont.)					
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.1a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=56)	<65 Years Avapritinib 25 mg (N=117)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=6)	P-Value [3]
Cognitive Effects (cont.)					
Memory impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mental impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mood altered, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.1a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=56)	<65 Years Avapritinib 25 mg (N=117)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=6)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.1a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=56)	<65 Years Avapritinib 25 mg (N=117)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=6)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.1a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=56)	<65 Years Avapritinib 25 mg (N=117)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=6)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.2a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=15)	Male Avapritinib 25 mg (N=35)	Female Placebo (N=52)	Female Avapritinib 25 mg (N=88)	P-Value [3]
Patients with at least one Serious AESI, n (%)	0	0	1 (1.9)	0	0.967
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.192	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.019 (-0.057, 0.018), 0.313	
Cognitive Effects, n (%)	0	0	1 (1.9)	0	0.967
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.192	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.019 (-0.057, 0.018), 0.313	
Mental status changes, n (%)	0	0	1 (1.9)	0	0.967
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.192	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.019 (-0.057, 0.018), 0.313	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.2a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=15)	Male Avapritinib 25 mg (N=35)	Female Placebo (N=52)	Female Avapritinib 25 mg (N=88)	P-Value [3]
Cognitive Effects (cont.)					
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Amnesia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.2a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=15)	Male Avapritinib 25 mg (N=35)	Female Placebo (N=52)	Female Avapritinib 25 mg (N=88)	P-Value [3]
Cognitive Effects (cont.)					
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.2a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=15)	Male Avapritinib 25 mg (N=35)	Female Placebo (N=52)	Female Avapritinib 25 mg (N=88)	P-Value [3]
Cognitive Effects (cont.)					
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.2a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=15)	Male Avapritinib 25 mg (N=35)	Female Placebo (N=52)	Female Avapritinib 25 mg (N=88)	P-Value [3]
Cognitive Effects (cont.)					
Memory impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mental impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mood altered, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.2a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=15)	Male Avapritinib 25 mg (N=35)	Female Placebo (N=52)	Female Avapritinib 25 mg (N=88)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.2a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=15)	Male Avapritinib 25 mg (N=35)	Female Placebo (N=52)	Female Avapritinib 25 mg (N=88)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.2a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=15)	Male Avapritinib 25 mg (N=35)	Female Placebo (N=52)	Female Avapritinib 25 mg (N=88)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.3a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=32)	North America Avapritinib 25 mg (N=52)	Europe Placebo (N=35)	Europe Avapritinib 25 mg (N=71)	P-Value [3]
Patients with at least one Serious AESI, n (%)	1 (3.1)	0	0	0	0.970
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.200		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.031 (-0.092, 0.029), 0.310		NA (NA, NA), NA	
Cognitive Effects, n (%)	1 (3.1)	0	0	0	0.970
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.200		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.031 (-0.092, 0.029), 0.310		NA (NA, NA), NA	
Mental status changes, n (%)	1 (3.1)	0	0	0	0.970
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.200		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.031 (-0.092, 0.029), 0.310		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.3a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=32)	North America Avapritinib 25 mg (N=52)	Europe Placebo (N=35)	Europe Avapritinib 25 mg (N=71)	P-Value [3]
Cognitive Effects (cont.)					
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Amnesia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.3a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=32)	North America Avapritinib 25 mg (N=52)	Europe Placebo (N=35)	Europe Avapritinib 25 mg (N=71)	P-Value [3]
Cognitive Effects (cont.)					
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.3a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=32)	North America Avapritinib 25 mg (N=52)	Europe Placebo (N=35)	Europe Avapritinib 25 mg (N=71)	P-Value [3]
Cognitive Effects (cont.)					
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.3a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=32)	North America Avapritinib 25 mg (N=52)	Europe Placebo (N=35)	Europe Avapritinib 25 mg (N=71)	P-Value [3]
Cognitive Effects (cont.)					
Memory impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mental impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mood altered, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.3a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=32)	North America Avapritinib 25 mg (N=52)	Europe Placebo (N=35)	Europe Avapritinib 25 mg (N=71)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.3a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=32)	North America Avapritinib 25 mg (N=52)	Europe Placebo (N=35)	Europe Avapritinib 25 mg (N=71)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.3a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=32)	North America Avapritinib 25 mg (N=52)	Europe Placebo (N=35)	Europe Avapritinib 25 mg (N=71)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=27)	United States Avapritinib 25 mg (N=44)	Germany Placebo (N=14)	Germany Avapritinib 25 mg (N=17)
Cognitive Effects, n (%)	1 (3.7)	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mental status changes, n (%)	1 (3.7)	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Agitation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Amnesia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Spain		France	
	Placebo (N=3)	Avapritinib 25 mg (N=13)	Placebo (N=5)	Avapritinib 25 mg (N=10)
Cognitive Effects, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mental status changes, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Agitation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Amnesia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=10)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Cognitive Effects, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mental status changes, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Agitation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Amnesia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=7)	Norway Placebo (N=2)	Norway Avapritinib 25 mg (N=5)
Cognitive Effects, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mental status changes, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Agitation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Amnesia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium		Italy	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=0)	Avapritinib 25 mg (N=3)
Cognitive Effects, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mental status changes, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Agitation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Amnesia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Switzerland		Sweden	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=1)	Avapritinib 25 mg (N=1)
Cognitive Effects, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mental status changes, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Agitation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Amnesia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Cognitive Effects, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Mental status changes, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Agitation, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Amnesia, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=27)	United States Avapritinib 25 mg (N=44)	Germany Placebo (N=14)	Germany Avapritinib 25 mg (N=17)
Cognitive Effects (cont.)	0	0	0	0
Cognitive disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Confusional state, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Delirium, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dementia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=13)	France Placebo (N=5)	France Avapritinib 25 mg (N=10)
Cognitive Effects (cont.)	0	0	0	0
Cognitive disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Confusional state, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Delirium, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dementia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=10)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Cognitive Effects (cont.)	0	0	0	0
Cognitive disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Confusional state, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Delirium, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dementia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=7)	Norway Placebo (N=2)	Norway Avapritinib 25 mg (N=5)
Cognitive Effects (cont.)	0	0	0	0
Cognitive disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Confusional state, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Delirium, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dementia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=2)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=3)
Cognitive Effects (cont.)	0	0	0	0
Cognitive disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Confusional state, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Delirium, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dementia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Switzerland Placebo (N=1)	Switzerland Avapritinib 25 mg (N=2)	Sweden Placebo (N=1)	Sweden Avapritinib 25 mg (N=1)
Cognitive Effects (cont.)	0	0	0	0
Cognitive disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Confusional state, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Delirium, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dementia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Cognitive Effects (cont.)	0	0	-
Cognitive disorder, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Confusional state, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Delirium, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Dementia, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=27)	United States Avapritinib 25 mg (N=44)	Germany Placebo (N=14)	Germany Avapritinib 25 mg (N=17)
Cognitive Effects (cont.)	0	0	0	0
Disorientation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Encephalopathy, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hallucination, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Memory impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=13)	France Placebo (N=5)	France Avapritinib 25 mg (N=10)
Cognitive Effects (cont.)	0	0	0	0
Disorientation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Encephalopathy, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hallucination, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Memory impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=10)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Cognitive Effects (cont.)	0	0	0	0
Disorientation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Encephalopathy, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hallucination, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Memory impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=7)	Norway Placebo (N=2)	Norway Avapritinib 25 mg (N=5)
Cognitive Effects (cont.)	0	0	0	0
Disorientation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Encephalopathy, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hallucination, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Memory impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=2)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=3)
Cognitive Effects (cont.)	0	0	0	0
Disorientation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Encephalopathy, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hallucination, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Memory impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Switzerland Placebo (N=1)	Switzerland Avapritinib 25 mg (N=2)	Sweden Placebo (N=1)	Sweden Avapritinib 25 mg (N=1)
Cognitive Effects (cont.)	0	0	0	0
Disorientation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Encephalopathy, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hallucination, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Memory impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Cognitive Effects (cont.)	0	0	-
Disorientation, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Hallucination, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Memory impairment, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=27)	United States Avapritinib 25 mg (N=44)	Germany Placebo (N=14)	Germany Avapritinib 25 mg (N=17)
Cognitive Effects (cont.)	0	0	0	0
Mental impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mood altered, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Personality change, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Psychotic disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=13)	France Placebo (N=5)	France Avapritinib 25 mg (N=10)
Cognitive Effects (cont.)	0	0	0	0
Mental impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mood altered, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Personality change, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Psychotic disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=10)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Cognitive Effects (cont.)	0	0	0	0
Mental impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mood altered, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Personality change, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Psychotic disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=7)	Norway Placebo (N=2)	Norway Avapritinib 25 mg (N=5)
Cognitive Effects (cont.)	0	0	0	0
Mental impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mood altered, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Personality change, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Psychotic disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=2)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=3)
Cognitive Effects (cont.)	0	0	0	0
Mental impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mood altered, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Personality change, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Psychotic disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Switzerland Placebo (N=1)	Switzerland Avapritinib 25 mg (N=2)	Sweden Placebo (N=1)	Sweden Avapritinib 25 mg (N=1)
Cognitive Effects (cont.)	0	0	0	0
Mental impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mood altered, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Personality change, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Psychotic disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Cognitive Effects (cont.)	0	0	-
Mental impairment, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Mood altered, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Personality change, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=27)	United States Avapritinib 25 mg (N=44)	Germany Placebo (N=14)	Germany Avapritinib 25 mg (N=17)
Cognitive Effects (cont.)	0	0	0	0
Somnolence, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Speech disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Intracranial Bleeding, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cerebral haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Spain		France	
	Placebo (N=3)	Avapritinib 25 mg (N=13)	Placebo (N=5)	Avapritinib 25 mg (N=10)
Cognitive Effects (cont.)	0	0	0	0
Somnolence, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Speech disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Intracranial Bleeding, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cerebral haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=10)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Cognitive Effects (cont.)	0	0	0	0
Somnolence, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Speech disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Intracranial Bleeding, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cerebral haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=7)	Norway Placebo (N=2)	Norway Avapritinib 25 mg (N=5)
Cognitive Effects (cont.)	0	0	0	0
Somnolence, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Speech disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Intracranial Bleeding, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cerebral haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=2)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=3)
Cognitive Effects (cont.)	0	0	0	0
Somnolence, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Speech disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Intracranial Bleeding, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cerebral haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Switzerland Placebo (N=1)	Switzerland Avapritinib 25 mg (N=2)	Sweden Placebo (N=1)	Sweden Avapritinib 25 mg (N=1)
Cognitive Effects (cont.)	0	0	0	0
Somnolence, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Speech disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Intracranial Bleeding, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cerebral haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Cognitive Effects (cont.)	0	0	-
Somnolence, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Speech disorder, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=27)	United States Avapritinib 25 mg (N=44)	Germany Placebo (N=14)	Germany Avapritinib 25 mg (N=17)
Intracranial Bleeding (cont.)	0	0	0	0
Cerebral haemorrhage, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Haemorrhage intracranial, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Subdural haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Spain		France	
	Placebo (N=3)	Avapritinib 25 mg (N=13)	Placebo (N=5)	Avapritinib 25 mg (N=10)
Intracranial Bleeding (cont.)	0	0	0	0
Cerebral haemorrhage, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Haemorrhage intracranial, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Subdural haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=10)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Intracranial Bleeding (cont.)	0	0	0	0
Cerebral haemorrhage, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Haemorrhage intracranial, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Subdural haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=7)	Norway Placebo (N=2)	Norway Avapritinib 25 mg (N=5)
Intracranial Bleeding (cont.)	0	0	0	0
Cerebral haemorrhage, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Haemorrhage intracranial, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Subdural haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=2)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=3)
Intracranial Bleeding (cont.)	0	0	0	0
Cerebral haemorrhage, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Haemorrhage intracranial, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Subdural haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Switzerland		Sweden	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=1)	Avapritinib 25 mg (N=1)
Intracranial Bleeding (cont.)	0	0	0	0
Cerebral haemorrhage, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Haemorrhage intracranial, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Subdural haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Intracranial Bleeding (cont.)	0	0	-
Cerebral haemorrhage, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.4a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=22)	Moderate Avapritinib 25 mg (N=37)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=86)	P-Value [3]
Patients with at least one Serious AESI, n (%)	1 (4.5)	0	0	0	0.964
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.191		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.045 (-0.132, 0.042), 0.306		NA (NA, NA), NA	
Cognitive Effects, n (%)	1 (4.5)	0	0	0	0.964
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.191		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.045 (-0.132, 0.042), 0.306		NA (NA, NA), NA	
Mental status changes, n (%)	1 (4.5)	0	0	0	0.964
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.191		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.045 (-0.132, 0.042), 0.306		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.4a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=22)	Moderate Avapritinib 25 mg (N=37)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=86)	P-Value [3]
Cognitive Effects (cont.)					
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Amnesia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.4a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=22)	Moderate Avapritinib 25 mg (N=37)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=86)	P-Value [3]
Cognitive Effects (cont.)					
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.4a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate		Severe		P-Value [3]
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	
Cognitive Effects (cont.)					
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.4a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate		Severe		P-Value [3]
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	
Cognitive Effects (cont.)					
Memory impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mental impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mood altered, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.4a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=22)	Moderate Avapritinib 25 mg (N=37)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=86)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.4a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=22)	Moderate Avapritinib 25 mg (N=37)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=86)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.4a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=22)	Moderate Avapritinib 25 mg (N=37)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=86)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.5a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=13)	<20 ng/mL Avapritinib 25 mg (N=26)	>=20 ng/mL Placebo (N=54)	>=20 ng/mL Avapritinib 25 mg (N=97)	P-Value [3]
Patients with at least one Serious AESI, n (%)	0	0	1 (1.9)	0	0.972
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.179	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.019 (-0.054, 0.017), 0.313	
Cognitive Effects, n (%)	0	0	1 (1.9)	0	0.972
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.179	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.019 (-0.054, 0.017), 0.313	
Mental status changes, n (%)	0	0	1 (1.9)	0	0.972
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.179	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.019 (-0.054, 0.017), 0.313	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.5a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=13)	<20 ng/mL Avapritinib 25 mg (N=26)	>=20 ng/mL Placebo (N=54)	>=20 ng/mL Avapritinib 25 mg (N=97)	P-Value [3]
Cognitive Effects (cont.)					
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Amnesia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.5a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=13)	<20 ng/mL Avapritinib 25 mg (N=26)	>=20 ng/mL Placebo (N=54)	>=20 ng/mL Avapritinib 25 mg (N=97)	P-Value [3]
Cognitive Effects (cont.)					
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.5a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=13)	<20 ng/mL Avapritinib 25 mg (N=26)	>=20 ng/mL Placebo (N=54)	>=20 ng/mL Avapritinib 25 mg (N=97)	P-Value [3]
Cognitive Effects (cont.)					
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.5a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=13)	<20 ng/mL Avapritinib 25 mg (N=26)	>=20 ng/mL Placebo (N=54)	>=20 ng/mL Avapritinib 25 mg (N=97)	P-Value [3]
Cognitive Effects (cont.)					
Memory impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mental impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mood altered, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.5a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=13)	<20 ng/mL Avapritinib 25 mg (N=26)	>=20 ng/mL Placebo (N=54)	>=20 ng/mL Avapritinib 25 mg (N=97)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.5a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=13)	<20 ng/mL Avapritinib 25 mg (N=26)	>=20 ng/mL Placebo (N=54)	>=20 ng/mL Avapritinib 25 mg (N=97)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.5a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=13)	<20 ng/mL Avapritinib 25 mg (N=26)	>=20 ng/mL Placebo (N=54)	>=20 ng/mL Avapritinib 25 mg (N=97)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.6a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=32)	 Avapritinib 25 mg (N=63)	Number of Baseline BSC >=4 Placebo (N=35)	 Avapritinib 25 mg (N=60)	P-Value [3]
Patients with at least one Serious AESI, n (%)	0	0	1 (2.9)	0	0.957
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.188	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.029 (-0.084, 0.027), 0.310	
Cognitive Effects, n (%)	0	0	1 (2.9)	0	0.957
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.188	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.029 (-0.084, 0.027), 0.310	
Mental status changes, n (%)	0	0	1 (2.9)	0	0.957
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.188	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.029 (-0.084, 0.027), 0.310	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.6a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=32)	 Avapritinib 25 mg (N=63)	Number of Baseline BSC >=4 Placebo (N=35)	 Avapritinib 25 mg (N=60)	P-Value [3]
Cognitive Effects (cont.)					
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Amnesia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.6a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=32)	 Avapritinib 25 mg (N=63)	Number of Baseline BSC >=4 Placebo (N=35)	 Avapritinib 25 mg (N=60)	P-Value [3]
Cognitive Effects (cont.)					
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.6a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=32)	 Avapritinib 25 mg (N=63)	Number of Baseline BSC >=4 Placebo (N=35)	 Avapritinib 25 mg (N=60)	P-Value [3]
Cognitive Effects (cont.)					
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
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[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.6a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=32)	 Avapritinib 25 mg (N=63)	Number of Baseline BSC >=4 Placebo (N=35)	 Avapritinib 25 mg (N=60)	P-Value [3]
Cognitive Effects (cont.)					
Memory impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mental impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mood altered, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
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Table 35.3.1.12.1.2.6a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=32)	 Avapritinib 25 mg (N=63)	Number of Baseline BSC >=4 Placebo (N=35)	 Avapritinib 25 mg (N=60)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.6a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=32)	 Avapritinib 25 mg (N=63)	Number of Baseline BSC >=4 Placebo (N=35)	 Avapritinib 25 mg (N=60)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.6a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=32)	 Avapritinib 25 mg (N=63)	Number of Baseline BSC >=4 Placebo (N=35)	 Avapritinib 25 mg (N=60)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.7a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=6)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=61)	No Avapritinib 25 mg (N=104)	P-Value [3]
Patients with at least one Serious AESI, n (%)	0	0	1 (1.6)	0	0.980
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.190	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.016 (-0.048, 0.015), 0.313	
Cognitive Effects, n (%)	0	0	1 (1.6)	0	0.980
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.190	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.016 (-0.048, 0.015), 0.313	
Mental status changes, n (%)	0	0	1 (1.6)	0	0.980
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.190	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.016 (-0.048, 0.015), 0.313	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.7a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=6)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=61)	No Avapritinib 25 mg (N=104)	P-Value [3]
Cognitive Effects (cont.)					
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Amnesia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.7a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=6)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=61)	No Avapritinib 25 mg (N=104)	P-Value [3]
Cognitive Effects (cont.)					
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.7a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes		No		P-Value [3]
	Placebo (N=6)	Avapritinib 25 mg (N=19)	Placebo (N=61)	Avapritinib 25 mg (N=104)	
Cognitive Effects (cont.)					
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.7a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes		No		P-Value [3]
	Placebo (N=6)	Avapritinib 25 mg (N=19)	Placebo (N=61)	Avapritinib 25 mg (N=104)	
Cognitive Effects (cont.)					
Memory impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mental impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mood altered, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.7a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes		No		P-Value [3]
	Placebo (N=6)	Avapritinib 25 mg (N=19)	Placebo (N=61)	Avapritinib 25 mg (N=104)	
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.7a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=6)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=61)	No Avapritinib 25 mg (N=104)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.7a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes		No		P-Value [3]
	Placebo (N=6)	Avapritinib 25 mg (N=19)	Placebo (N=61)	Avapritinib 25 mg (N=104)	
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.8a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes		No		P-Value [3]
	Placebo (N=11)	Avapritinib 25 mg (N=25)	Placebo (N=56)	Avapritinib 25 mg (N=98)	
Patients with at least one Serious AESI, n (%)	0	0	1 (1.8)	0	0.973
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.184	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.018 (-0.053, 0.017), 0.313	
Cognitive Effects, n (%)	0	0	1 (1.8)	0	0.973
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.184	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.018 (-0.053, 0.017), 0.313	
Mental status changes, n (%)	0	0	1 (1.8)	0	0.973
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.184	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.018 (-0.053, 0.017), 0.313	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.8a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=25)	No Placebo (N=56)	No Avapritinib 25 mg (N=98)	P-Value [3]
Cognitive Effects (cont.)					
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Amnesia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.8a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=25)	No Placebo (N=56)	No Avapritinib 25 mg (N=98)	P-Value [3]
Cognitive Effects (cont.)					
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.8a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=25)	No Placebo (N=56)	No Avapritinib 25 mg (N=98)	P-Value [3]
Cognitive Effects (cont.)					
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.8a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=25)	No Placebo (N=56)	No Avapritinib 25 mg (N=98)	P-Value [3]
Cognitive Effects (cont.)					
Memory impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mental impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mood altered, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.8a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=25)	No Placebo (N=56)	No Avapritinib 25 mg (N=98)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.8a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=25)	No Placebo (N=56)	No Avapritinib 25 mg (N=98)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.12.1.2.8a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=25)	No Placebo (N=56)	No Avapritinib 25 mg (N=98)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.1a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=56)	<65 Years Avapritinib 25 mg (N=117)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=6)	P-Value [3]
Patients with at least one Grade 1 and 2 AESI, n (%)	2 (3.6)	4 (3.4)	0	0	>0.999
Odds Ratio (95% CIs) [1], P-Value		0.956 (0.170, 5.381), 0.959		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		0.957 (0.181, 5.071), 0.959		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.002 (-0.060, 0.057), 0.959		NA (NA, NA), NA	
Cognitive Effects, n (%)	2 (3.6)	4 (3.4)	0	0	>0.999
Odds Ratio (95% CIs) [1], P-Value		0.956 (0.170, 5.381), 0.959		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		0.957 (0.181, 5.071), 0.959		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.002 (-0.060, 0.057), 0.959		NA (NA, NA), NA	
Memory impairment, n (%)	1 (1.8)	2 (1.7)	0	0	>0.999
Odds Ratio (95% CIs) [1], P-Value		0.957 (0.085, 10.777), 0.971		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		0.957 (0.089, 10.335), 0.971		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.001 (-0.043, 0.041), 0.972		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.1a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=56)	<65 Years Avapritinib 25 mg (N=117)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=6)	P-Value [3]
Cognitive Effects (cont.)					
Amnesia, n (%)	0	1 (0.9)	0	0	0.983
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.488		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.009 (-0.008, 0.025), 0.315		NA (NA, NA), NA	
Mood altered, n (%)	0	1 (0.9)	0	0	0.983
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.488		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.009 (-0.008, 0.025), 0.315		NA (NA, NA), NA	
Mental impairment, n (%)	1 (1.8)	0	0	0	0.982
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.147		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.018 (-0.053, 0.017), 0.313		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.1a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=56)	<65 Years Avapritinib 25 mg (N=117)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=6)	P-Value [3]
Cognitive Effects (cont.)					
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.1a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=56)	<65 Years Avapritinib 25 mg (N=117)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=6)	P-Value [3]
Cognitive Effects (cont.)					
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.1a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=56)	<65 Years Avapritinib 25 mg (N=117)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=6)	P-Value [3]
Cognitive Effects (cont.)					
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mental status changes, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.1a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=56)	<65 Years Avapritinib 25 mg (N=117)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=6)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.1a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=56)	<65 Years Avapritinib 25 mg (N=117)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=6)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.1a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=56)	<65 Years Avapritinib 25 mg (N=117)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=6)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.2a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=15)	Male Avapritinib 25 mg (N=35)	Female Placebo (N=52)	Female Avapritinib 25 mg (N=88)	P-Value [3]
Patients with at least one Grade 1 and 2 AESI, n (%)	1 (6.7)	1 (2.9)	1 (1.9)	3 (3.4)	0.428
Odds Ratio (95% CIs) [1], P-Value		0.412 (0.024, 7.053), 0.529		1.800 (0.182, 17.769), 0.610	
Relative Risk (95% CIs) [2], P-Value		0.429 (0.029, 6.409), 0.539		1.773 (0.189, 16.603), 0.616	
Risk Difference (95% CIs) [2], P-Value		-0.038 (-0.176, 0.100), 0.588		0.015 (-0.038, 0.068), 0.584	
Cognitive Effects, n (%)	1 (6.7)	1 (2.9)	1 (1.9)	3 (3.4)	0.428
Odds Ratio (95% CIs) [1], P-Value		0.412 (0.024, 7.053), 0.529		1.800 (0.182, 17.769), 0.610	
Relative Risk (95% CIs) [2], P-Value		0.429 (0.029, 6.409), 0.539		1.773 (0.189, 16.603), 0.616	
Risk Difference (95% CIs) [2], P-Value		-0.038 (-0.176, 0.100), 0.588		0.015 (-0.038, 0.068), 0.584	
Memory impairment, n (%)	1 (6.7)	1 (2.9)	0	1 (1.1)	0.947
Odds Ratio (95% CIs) [1], P-Value		0.412 (0.024, 7.053), 0.529		NE (NE, NE), 0.440	
Relative Risk (95% CIs) [2], P-Value		0.429 (0.029, 6.409), 0.539		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.038 (-0.176, 0.100), 0.588		0.011 (-0.011, 0.034), 0.315	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.2a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=15)	Male Avapritinib 25 mg (N=35)	Female Placebo (N=52)	Female Avapritinib 25 mg (N=88)	P-Value [3]
Cognitive Effects (cont.)					
Amnesia, n (%)	0	0	0	1 (1.1)	0.973
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.440	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.011 (-0.011, 0.034), 0.315	
Mood altered, n (%)	0	0	0	1 (1.1)	0.973
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.440	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.011 (-0.011, 0.034), 0.315	
Mental impairment, n (%)	0	0	1 (1.9)	0	0.967
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.192	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.019 (-0.057, 0.018), 0.313	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.2a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=15)	Male Avapritinib 25 mg (N=35)	Female Placebo (N=52)	Female Avapritinib 25 mg (N=88)	P-Value [3]
Cognitive Effects (cont.)					
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
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[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.11.2.2.2a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=15)	Male Avapritinib 25 mg (N=35)	Female Placebo (N=52)	Female Avapritinib 25 mg (N=88)	P-Value [3]
Cognitive Effects (cont.)					
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.2a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=15)	Male Avapritinib 25 mg (N=35)	Female Placebo (N=52)	Female Avapritinib 25 mg (N=88)	P-Value [3]
Cognitive Effects (cont.)					
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mental status changes, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.2a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=15)	Male Avapritinib 25 mg (N=35)	Female Placebo (N=52)	Female Avapritinib 25 mg (N=88)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.2a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=15)	Male Avapritinib 25 mg (N=35)	Female Placebo (N=52)	Female Avapritinib 25 mg (N=88)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-pp-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.2.2a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=15)	Male Avapritinib 25 mg (N=35)	Female Placebo (N=52)	Female Avapritinib 25 mg (N=88)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-pp-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.2.3a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=32)	North America Avapritinib 25 mg (N=52)	Europe Placebo (N=35)	Europe Avapritinib 25 mg (N=71)	P-Value [3]
Patients with at least one Grade 1 and 2 AESI, n (%)	1 (3.1)	2 (3.8)	1 (2.9)	2 (2.8)	0.896
Odds Ratio (95% CIs) [1], P-Value		1.240 (0.108, 14.254), 0.863		0.986 (0.086, 11.254), 0.991	
Relative Risk (95% CIs) [2], P-Value		1.231 (0.116, 13.031), 0.863		0.986 (0.093, 10.505), 0.991	
Risk Difference (95% CIs) [2], P-Value		0.007 (-0.073, 0.087), 0.859		-0.000 (-0.068, 0.067), 0.991	
Cognitive Effects, n (%)	1 (3.1)	2 (3.8)	1 (2.9)	2 (2.8)	0.896
Odds Ratio (95% CIs) [1], P-Value		1.240 (0.108, 14.254), 0.863		0.986 (0.086, 11.254), 0.991	
Relative Risk (95% CIs) [2], P-Value		1.231 (0.116, 13.031), 0.863		0.986 (0.093, 10.505), 0.991	
Risk Difference (95% CIs) [2], P-Value		0.007 (-0.073, 0.087), 0.859		-0.000 (-0.068, 0.067), 0.991	
Memory impairment, n (%)	1 (3.1)	2 (3.8)	0	0	0.999
Odds Ratio (95% CIs) [1], P-Value		1.240 (0.108, 14.254), 0.863		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		1.231 (0.116, 13.031), 0.863		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.007 (-0.073, 0.087), 0.859		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.3a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=32)	North America Avapritinib 25 mg (N=52)	Europe Placebo (N=35)	Europe Avapritinib 25 mg (N=71)	P-Value [3]
Cognitive Effects (cont.)					
Amnesia, n (%)	0	0	0	1 (1.4)	0.966
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.481	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.014 (-0.013, 0.041), 0.314	
Mood altered, n (%)	0	0	0	1 (1.4)	0.966
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.481	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.014 (-0.013, 0.041), 0.314	
Mental impairment, n (%)	0	0	1 (2.9)	0	0.957
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.152	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.029 (-0.084, 0.027), 0.310	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.3a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=32)	North America Avapritinib 25 mg (N=52)	Europe Placebo (N=35)	Europe Avapritinib 25 mg (N=71)	P-Value [3]
Cognitive Effects (cont.)					
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.3a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=32)	North America Avapritinib 25 mg (N=52)	Europe Placebo (N=35)	Europe Avapritinib 25 mg (N=71)	P-Value [3]
Cognitive Effects (cont.)					
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.11.2.2.3a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=32)	North America Avapritinib 25 mg (N=52)	Europe Placebo (N=35)	Europe Avapritinib 25 mg (N=71)	P-Value [3]
Cognitive Effects (cont.)					
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mental status changes, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.3a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=32)	North America Avapritinib 25 mg (N=52)	Europe Placebo (N=35)	Europe Avapritinib 25 mg (N=71)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.3a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=32)	North America Avapritinib 25 mg (N=52)	Europe Placebo (N=35)	Europe Avapritinib 25 mg (N=71)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.3a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=32)	North America Avapritinib 25 mg (N=52)	Europe Placebo (N=35)	Europe Avapritinib 25 mg (N=71)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=27)	United States Avapritinib 25 mg (N=44)	Germany Placebo (N=14)	Germany Avapritinib 25 mg (N=17)
Cognitive Effects, n (%)	1 (3.7)	2 (4.5)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Memory impairment, n (%)	1 (3.7)	2 (4.5)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Amnesia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mood altered, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=13)	France Placebo (N=5)	France Avapritinib 25 mg (N=10)
Cognitive Effects, n (%)	0	1 (7.7)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Memory impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Amnesia, n (%)	0	1 (7.7)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mood altered, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=10)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Cognitive Effects, n (%)	1 (20.0)	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Memory impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Amnesia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mood altered, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands		Norway	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)
Cognitive Effects, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Memory impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Amnesia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mood altered, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=2)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=3)
Cognitive Effects, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Memory impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Amnesia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mood altered, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Switzerland Placebo (N=1)	Switzerland Avapritinib 25 mg (N=2)	Sweden Placebo (N=1)	Sweden Avapritinib 25 mg (N=1)
Cognitive Effects, n (%)	0	1 (50.0)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Memory impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Amnesia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mood altered, n (%)	0	1 (50.0)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Cognitive Effects, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Memory impairment, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Amnesia, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Mood altered, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=27)	United States Avapritinib 25 mg (N=44)	Germany Placebo (N=14)	Germany Avapritinib 25 mg (N=17)
Cognitive Effects (cont.)	0	0	0	0
Mental impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Agitation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cognitive disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Confusional state, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=13)	France Placebo (N=5)	France Avapritinib 25 mg (N=10)
Cognitive Effects (cont.)	0	0	0	0
Mental impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Agitation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cognitive disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Confusional state, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=10)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Cognitive Effects (cont.)	1 (20.0)	0	0	0
Mental impairment, n (%)	1 (20.0)	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Agitation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cognitive disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Confusional state, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=7)	Norway Placebo (N=2)	Norway Avapritinib 25 mg (N=5)
Cognitive Effects (cont.)	0	0	0	0
Mental impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Agitation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cognitive disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Confusional state, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=2)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=3)
Cognitive Effects (cont.)	0	0	0	0
Mental impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Agitation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cognitive disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Confusional state, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Switzerland Placebo (N=1)	Switzerland Avapritinib 25 mg (N=2)	Sweden Placebo (N=1)	Sweden Avapritinib 25 mg (N=1)
Cognitive Effects (cont.)	0	0	0	0
Mental impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Agitation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cognitive disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Confusional state, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Cognitive Effects (cont.)	0	0	-
Mental impairment, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Agitation, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Confusional state, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=27)	United States Avapritinib 25 mg (N=44)	Germany Placebo (N=14)	Germany Avapritinib 25 mg (N=17)
Cognitive Effects (cont.)	0	0	0	0
Delirium, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dementia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Disorientation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Encephalopathy, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=13)	France Placebo (N=5)	France Avapritinib 25 mg (N=10)
Cognitive Effects (cont.)	0	0	0	0
Delirium, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dementia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Disorientation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Encephalopathy, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=10)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Cognitive Effects (cont.)	0	0	0	0
Delirium, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dementia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Disorientation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Encephalopathy, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=7)	Norway Placebo (N=2)	Norway Avapritinib 25 mg (N=5)
Cognitive Effects (cont.)	0	0	0	0
Delirium, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dementia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Disorientation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Encephalopathy, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=2)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=3)
Cognitive Effects (cont.)	0	0	0	0
Delirium, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dementia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Disorientation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Encephalopathy, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Switzerland Placebo (N=1)	Switzerland Avapritinib 25 mg (N=2)	Sweden Placebo (N=1)	Sweden Avapritinib 25 mg (N=1)
Cognitive Effects (cont.)	0	0	0	0
Delirium, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dementia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Disorientation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Encephalopathy, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Cognitive Effects (cont.)	0	0	-
Delirium, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Dementia, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Disorientation, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=27)	United States Avapritinib 25 mg (N=44)	Germany Placebo (N=14)	Germany Avapritinib 25 mg (N=17)
Cognitive Effects (cont.)	0	0	0	0
Hallucination, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mental status changes, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Personality change, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Psychotic disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=13)	France Placebo (N=5)	France Avapritinib 25 mg (N=10)
Cognitive Effects (cont.)	0	0	0	0
Hallucination, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mental status changes, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Personality change, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Psychotic disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=10)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Cognitive Effects (cont.)	0	0	0	0
Hallucination, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mental status changes, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Personality change, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Psychotic disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=7)	Norway Placebo (N=2)	Norway Avapritinib 25 mg (N=5)
Cognitive Effects (cont.)	0	0	0	0
Hallucination, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mental status changes, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Personality change, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Psychotic disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=2)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=3)
Cognitive Effects (cont.)	0	0	0	0
Hallucination, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mental status changes, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Personality change, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Psychotic disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Switzerland Placebo (N=1)	Switzerland Avapritinib 25 mg (N=2)	Sweden Placebo (N=1)	Sweden Avapritinib 25 mg (N=1)
Cognitive Effects (cont.)	0	0	0	0
Hallucination, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mental status changes, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Personality change, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Psychotic disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Cognitive Effects (cont.)	0	0	-
Hallucination, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Mental status changes, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Personality change, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=27)	United States Avapritinib 25 mg (N=44)	Germany Placebo (N=14)	Germany Avapritinib 25 mg (N=17)
Cognitive Effects (cont.)	0	0	0	0
Somnolence, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Speech disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Intracranial Bleeding, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cerebral haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=13)	France Placebo (N=5)	France Avapritinib 25 mg (N=10)
Cognitive Effects (cont.)	0	0	0	0
Somnolence, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Speech disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Intracranial Bleeding, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cerebral haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=10)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Cognitive Effects (cont.)	0	0	0	0
Somnolence, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Speech disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Intracranial Bleeding, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cerebral haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=7)	Norway Placebo (N=2)	Norway Avapritinib 25 mg (N=5)
Cognitive Effects (cont.)	0	0	0	0
Somnolence, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Speech disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Intracranial Bleeding, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cerebral haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=2)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=3)
Cognitive Effects (cont.)	0	0	0	0
Somnolence, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Speech disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Intracranial Bleeding, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cerebral haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Switzerland Placebo (N=1)	Switzerland Avapritinib 25 mg (N=2)	Sweden Placebo (N=1)	Sweden Avapritinib 25 mg (N=1)
Cognitive Effects (cont.)	0	0	0	0
Somnolence, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Speech disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Intracranial Bleeding, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cerebral haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Cognitive Effects (cont.)	0	0	-
Somnolence, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Speech disorder, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=27)	United States Avapritinib 25 mg (N=44)	Germany Placebo (N=14)	Germany Avapritinib 25 mg (N=17)
Intracranial Bleeding (cont.)	0	0	0	0
Cerebral haemorrhage, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Haemorrhage intracranial, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Subdural haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=13)	France Placebo (N=5)	France Avapritinib 25 mg (N=10)
Intracranial Bleeding (cont.)	0	0	0	0
Cerebral haemorrhage, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Haemorrhage intracranial, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Subdural haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=10)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Intracranial Bleeding (cont.)	0	0	0	0
Cerebral haemorrhage, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Haemorrhage intracranial, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Subdural haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=7)	Norway Placebo (N=2)	Norway Avapritinib 25 mg (N=5)
Intracranial Bleeding (cont.)	0	0	0	0
Cerebral haemorrhage, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Haemorrhage intracranial, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Subdural haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=2)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=3)
Intracranial Bleeding (cont.)	0	0	0	0
Cerebral haemorrhage, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Haemorrhage intracranial, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Subdural haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Switzerland		Sweden	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=1)	Avapritinib 25 mg (N=1)
Intracranial Bleeding (cont.)	0	0	0	0
Cerebral haemorrhage, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Haemorrhage intracranial, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Subdural haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Intracranial Bleeding (cont.)	0	0	-
Cerebral haemorrhage, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-pp-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.2.2.4a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=22)	Moderate Avapritinib 25 mg (N=37)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=86)	P-Value [3]
Patients with at least one Grade 1 and 2 AESI, n (%)	1 (4.5)	1 (2.7)	1 (2.2)	3 (3.5)	0.589
Odds Ratio (95% CIs) [1], P-Value		0.583 (0.035, 9.822), 0.705		1.590 (0.161, 15.744), 0.689	
Relative Risk (95% CIs) [2], P-Value		0.595 (0.039, 9.036), 0.708		1.570 (0.168, 14.661), 0.692	
Risk Difference (95% CIs) [2], P-Value		-0.018 (-0.120, 0.083), 0.722		0.013 (-0.045, 0.071), 0.669	
Cognitive Effects, n (%)	1 (4.5)	1 (2.7)	1 (2.2)	3 (3.5)	0.589
Odds Ratio (95% CIs) [1], P-Value		0.583 (0.035, 9.822), 0.705		1.590 (0.161, 15.744), 0.689	
Relative Risk (95% CIs) [2], P-Value		0.595 (0.039, 9.036), 0.708		1.570 (0.168, 14.661), 0.692	
Risk Difference (95% CIs) [2], P-Value		-0.018 (-0.120, 0.083), 0.722		0.013 (-0.045, 0.071), 0.669	
Memory impairment, n (%)	1 (4.5)	1 (2.7)	0	1 (1.2)	0.954
Odds Ratio (95% CIs) [1], P-Value		0.583 (0.035, 9.822), 0.705		NE (NE, NE), 0.468	
Relative Risk (95% CIs) [2], P-Value		0.595 (0.039, 9.036), 0.708		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.018 (-0.120, 0.083), 0.722		0.012 (-0.011, 0.034), 0.314	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.4a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=22)	Moderate Avapritinib 25 mg (N=37)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=86)	P-Value [3]
Cognitive Effects (cont.)					
Amnesia, n (%)	0	0	0	1 (1.2)	0.970
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.468	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.012 (-0.011, 0.034), 0.314	
Mood altered, n (%)	0	0	0	1 (1.2)	0.970
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.468	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.012 (-0.011, 0.034), 0.314	
Mental impairment, n (%)	0	0	1 (2.2)	0	0.965
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.165	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.022 (-0.065, 0.021), 0.312	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.4a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=22)	Moderate Avapritinib 25 mg (N=37)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=86)	P-Value [3]
Cognitive Effects (cont.)					
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.4a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=22)	Moderate Avapritinib 25 mg (N=37)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=86)	P-Value [3]
Cognitive Effects (cont.)					
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.4a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=22)	Moderate Avapritinib 25 mg (N=37)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=86)	P-Value [3]
Cognitive Effects (cont.)					
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mental status changes, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.4a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=22)	Moderate Avapritinib 25 mg (N=37)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=86)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.4a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=22)	Moderate Avapritinib 25 mg (N=37)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=86)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.4a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=22)	Moderate Avapritinib 25 mg (N=37)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=86)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.5a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=13)	<20 ng/mL Avapritinib 25 mg (N=26)	>=20 ng/mL Placebo (N=54)	>=20 ng/mL Avapritinib 25 mg (N=97)	P-Value [3]
Patients with at least one Grade 1 and 2 AESI, n (%)	1 (7.7)	0	1 (1.9)	4 (4.1)	0.963
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.152		2.280 (0.248, 20.928), 0.455	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		2.227 (0.255, 19.423), 0.469	
Risk Difference (95% CIs) [2], P-Value		-0.077 (-0.222, 0.068), 0.298		0.023 (-0.031, 0.076), 0.405	
Cognitive Effects, n (%)	1 (7.7)	0	1 (1.9)	4 (4.1)	0.963
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.152		2.280 (0.248, 20.928), 0.455	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		2.227 (0.255, 19.423), 0.469	
Risk Difference (95% CIs) [2], P-Value		-0.077 (-0.222, 0.068), 0.298		0.023 (-0.031, 0.076), 0.405	
Memory impairment, n (%)	1 (7.7)	0	0	2 (2.1)	0.927
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.152		NE (NE, NE), 0.288	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.077 (-0.222, 0.068), 0.298		0.021 (-0.008, 0.049), 0.153	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.5a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=13)	<20 ng/mL Avapritinib 25 mg (N=26)	>=20 ng/mL Placebo (N=54)	>=20 ng/mL Avapritinib 25 mg (N=97)	P-Value [3]
Cognitive Effects (cont.)					
Amnesia, n (%)	0	0	0	1 (1.0)	0.975
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.454	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.010 (-0.010, 0.030), 0.315	
Mood altered, n (%)	0	0	0	1 (1.0)	0.975
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.454	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.010 (-0.010, 0.030), 0.315	
Mental impairment, n (%)	0	0	1 (1.9)	0	0.972
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.179	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.019 (-0.054, 0.017), 0.313	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.5a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=13)	<20 ng/mL Avapritinib 25 mg (N=26)	>=20 ng/mL Placebo (N=54)	>=20 ng/mL Avapritinib 25 mg (N=97)	P-Value [3]
Cognitive Effects (cont.)					
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.5a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=13)	<20 ng/mL Avapritinib 25 mg (N=26)	>=20 ng/mL Placebo (N=54)	>=20 ng/mL Avapritinib 25 mg (N=97)	P-Value [3]
Cognitive Effects (cont.)					
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.5a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=13)	<20 ng/mL Avapritinib 25 mg (N=26)	>=20 ng/mL Placebo (N=54)	>=20 ng/mL Avapritinib 25 mg (N=97)	P-Value [3]
Cognitive Effects (cont.)					
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mental status changes, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-pp-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.2.5a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=13)	<20 ng/mL Avapritinib 25 mg (N=26)	>=20 ng/mL Placebo (N=54)	>=20 ng/mL Avapritinib 25 mg (N=97)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-pp-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.2.5a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=13)	<20 ng/mL Avapritinib 25 mg (N=26)	>=20 ng/mL Placebo (N=54)	>=20 ng/mL Avapritinib 25 mg (N=97)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-pp-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.2.5a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=13)	<20 ng/mL Avapritinib 25 mg (N=26)	>=20 ng/mL Placebo (N=54)	>=20 ng/mL Avapritinib 25 mg (N=97)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-pp-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.2.6a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
AESI Category Preferred Term	Placebo (N=32)	Avapritinib 25 mg (N=63)	Placebo (N=35)	Avapritinib 25 mg (N=60)	P-Value [3]
Patients with at least one Grade 1 and 2 AESI, n (%)	0	0	2 (5.7)	4 (6.7)	>0.999
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		1.179 (0.205, 6.789), 0.854	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		1.167 (0.225, 6.047), 0.854	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.010 (-0.090, 0.109), 0.851	
Cognitive Effects, n (%)	0	0	2 (5.7)	4 (6.7)	>0.999
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		1.179 (0.205, 6.789), 0.854	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		1.167 (0.225, 6.047), 0.854	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.010 (-0.090, 0.109), 0.851	
Memory impairment, n (%)	0	0	1 (2.9)	2 (3.3)	>0.999
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		1.172 (0.102, 13.418), 0.898	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		1.167 (0.110, 12.405), 0.898	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.005 (-0.067, 0.076), 0.896	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.6a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=32)	Number of Baseline BSC <4 Avapritinib 25 mg (N=63)	Number of Baseline BSC >=4 Placebo (N=35)	Number of Baseline BSC >=4 Avapritinib 25 mg (N=60)	P-Value [3]
Cognitive Effects (cont.)					
Amnesia, n (%)	0	0	0	1 (1.7)	0.965
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.443	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.017 (-0.016, 0.049), 0.313	
Mood altered, n (%)	0	0	0	1 (1.7)	0.965
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.443	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.017 (-0.016, 0.049), 0.313	
Mental impairment, n (%)	0	0	1 (2.9)	0	0.957
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.188	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.029 (-0.084, 0.027), 0.310	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.6a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=32)	 Avapritinib 25 mg (N=63)	Number of Baseline BSC >=4 Placebo (N=35)	 Avapritinib 25 mg (N=60)	P-Value [3]
Cognitive Effects (cont.)					
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.6a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=32)	 Avapritinib 25 mg (N=63)	Number of Baseline BSC >=4 Placebo (N=35)	 Avapritinib 25 mg (N=60)	P-Value [3]
Cognitive Effects (cont.)					
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.6a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=32)	 Avapritinib 25 mg (N=63)	Number of Baseline BSC >=4 Placebo (N=35)	 Avapritinib 25 mg (N=60)	P-Value [3]
Cognitive Effects (cont.)					
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mental status changes, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.6a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=32)	 Avapritinib 25 mg (N=63)	Number of Baseline BSC >=4 Placebo (N=35)	 Avapritinib 25 mg (N=60)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.6a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=32)	 Avapritinib 25 mg (N=63)	Number of Baseline BSC >=4 Placebo (N=35)	 Avapritinib 25 mg (N=60)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.6a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=32)	 Avapritinib 25 mg (N=63)	Number of Baseline BSC >=4 Placebo (N=35)	 Avapritinib 25 mg (N=60)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.7a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=6)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=61)	No Avapritinib 25 mg (N=104)	P-Value [3]
Patients with at least one Grade 1 and 2 AESI, n (%)	0	1 (5.3)	2 (3.3)	3 (2.9)	0.963
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.566		0.876 (0.142, 5.396), 0.887	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.880 (0.151, 5.119), 0.887	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		-0.004 (-0.059, 0.051), 0.888	
Cognitive Effects, n (%)	0	1 (5.3)	2 (3.3)	3 (2.9)	0.963
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.566		0.876 (0.142, 5.396), 0.887	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.880 (0.151, 5.119), 0.887	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		-0.004 (-0.059, 0.051), 0.888	
Memory impairment, n (%)	0	0	1 (1.6)	2 (1.9)	>0.999
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		1.176 (0.104, 13.251), 0.895	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		1.173 (0.109, 12.669), 0.895	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.003 (-0.039, 0.044), 0.893	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.7a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=6)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=61)	No Avapritinib 25 mg (N=104)	P-Value [3]
Cognitive Effects (cont.)					
Amnesia, n (%)	0	0	0	1 (1.0)	0.981
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.442	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.010 (-0.009, 0.028), 0.315	
Mood altered, n (%)	0	1 (5.3)	0	0	0.960
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.566		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		NA (NA, NA), NA	
Mental impairment, n (%)	0	0	1 (1.6)	0	0.980
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.190	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.016 (-0.048, 0.015), 0.313	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=6)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=61)	No Avapritinib 25 mg (N=104)	P-Value [3]
Cognitive Effects (cont.)					
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.7a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=6)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=61)	No Avapritinib 25 mg (N=104)	P-Value [3]
Cognitive Effects (cont.)					
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.7a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes		No		P-Value [3]
	Placebo (N=6)	Avapritinib 25 mg (N=19)	Placebo (N=61)	Avapritinib 25 mg (N=104)	
Cognitive Effects (cont.)					
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mental status changes, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.7a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=6)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=61)	No Avapritinib 25 mg (N=104)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.7a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=6)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=61)	No Avapritinib 25 mg (N=104)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.7a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=6)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=61)	No Avapritinib 25 mg (N=104)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.8a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes		No		P-Value [3]
	Placebo (N=11)	Avapritinib 25 mg (N=25)	Placebo (N=56)	Avapritinib 25 mg (N=98)	
Patients with at least one Grade 1 and 2 AESI, n (%)	0	1 (4.0)	2 (3.6)	3 (3.1)	0.951
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.501		0.853 (0.138, 5.263), 0.864	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.857 (0.148, 4.976), 0.864	
Risk Difference (95% CIs) [2], P-Value		0.040 (-0.037, 0.117), 0.307		-0.005 (-0.064, 0.054), 0.866	
Cognitive Effects, n (%)	0	1 (4.0)	2 (3.6)	3 (3.1)	0.951
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.501		0.853 (0.138, 5.263), 0.864	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.857 (0.148, 4.976), 0.864	
Risk Difference (95% CIs) [2], P-Value		0.040 (-0.037, 0.117), 0.307		-0.005 (-0.064, 0.054), 0.866	
Memory impairment, n (%)	0	0	1 (1.8)	2 (2.0)	>0.999
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		1.146 (0.102, 12.928), 0.912	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		1.143 (0.106, 12.323), 0.912	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.003 (-0.042, 0.047), 0.911	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.8a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=25)	No Placebo (N=56)	No Avapritinib 25 mg (N=98)	P-Value [3]
Cognitive Effects (cont.)					
Amnesia, n (%)	0	0	0	1 (1.0)	0.976
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.448	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.010 (-0.010, 0.030), 0.315	
Mood altered, n (%)	0	1 (4.0)	0	0	0.955
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.501		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.040 (-0.037, 0.117), 0.307		NA (NA, NA), NA	
Mental impairment, n (%)	0	0	1 (1.8)	0	0.973
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.184	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.018 (-0.053, 0.017), 0.313	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
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Table 35.3.1.11.2.2.8a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=25)	No Placebo (N=56)	No Avapritinib 25 mg (N=98)	P-Value [3]
Cognitive Effects (cont.)					
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.8a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=25)	No Placebo (N=56)	No Avapritinib 25 mg (N=98)	P-Value [3]
Cognitive Effects (cont.)					
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.8a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=25)	No Placebo (N=56)	No Avapritinib 25 mg (N=98)	P-Value [3]
Cognitive Effects (cont.)					
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mental status changes, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.8a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=25)	No Placebo (N=56)	No Avapritinib 25 mg (N=98)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.2.2.8a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=25)	No Placebo (N=56)	No Avapritinib 25 mg (N=98)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-pp-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.2.8a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=25)	No Placebo (N=56)	No Avapritinib 25 mg (N=98)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.1a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=56)	<65 Years Avapritinib 25 mg (N=117)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=6)	P-Value [3]
Patients with at least one Grade 3 and Higher AESI, n (%)	0	0	1 (9.1)	0	0.967
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.446	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.091 (-0.261, 0.079), 0.294	
Cognitive Effects, n (%)	0	0	1 (9.1)	0	0.967
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.446	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.091 (-0.261, 0.079), 0.294	
Mental status changes, n (%)	0	0	1 (9.1)	0	0.967
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.446	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.091 (-0.261, 0.079), 0.294	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.1a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=56)	<65 Years Avapritinib 25 mg (N=117)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=6)	P-Value [3]
Cognitive Effects (cont.)					
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Amnesia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-pp-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.2.1a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=56)	<65 Years Avapritinib 25 mg (N=117)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=6)	P-Value [3]
Cognitive Effects (cont.)					
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.1a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=56)	<65 Years Avapritinib 25 mg (N=117)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=6)	P-Value [3]
Cognitive Effects (cont.)					
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.1a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=56)	<65 Years Avapritinib 25 mg (N=117)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=6)	P-Value [3]
Cognitive Effects (cont.)					
Memory impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mental impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mood altered, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.1a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=56)	<65 Years Avapritinib 25 mg (N=117)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=6)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.1a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=56)	<65 Years Avapritinib 25 mg (N=117)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=6)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.1a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=56)	<65 Years Avapritinib 25 mg (N=117)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=6)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.2a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=15)	Male Avapritinib 25 mg (N=35)	Female Placebo (N=52)	Female Avapritinib 25 mg (N=88)	P-Value [3]
Patients with at least one Grade 3 and Higher AESI, n (%)	0	0	1 (1.9)	0	0.967
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.192	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.019 (-0.057, 0.018), 0.313	
Cognitive Effects, n (%)	0	0	1 (1.9)	0	0.967
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.192	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.019 (-0.057, 0.018), 0.313	
Mental status changes, n (%)	0	0	1 (1.9)	0	0.967
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.192	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.019 (-0.057, 0.018), 0.313	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-pp-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.2.2a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=15)	Male Avapritinib 25 mg (N=35)	Female Placebo (N=52)	Female Avapritinib 25 mg (N=88)	P-Value [3]
Cognitive Effects (cont.)					
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Amnesia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-pp-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.2.2a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=15)	Male Avapritinib 25 mg (N=35)	Female Placebo (N=52)	Female Avapritinib 25 mg (N=88)	P-Value [3]
Cognitive Effects (cont.)					
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.2a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=15)	Male Avapritinib 25 mg (N=35)	Female Placebo (N=52)	Female Avapritinib 25 mg (N=88)	P-Value [3]
Cognitive Effects (cont.)					
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.2a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=15)	Male Avapritinib 25 mg (N=35)	Female Placebo (N=52)	Female Avapritinib 25 mg (N=88)	P-Value [3]
Cognitive Effects (cont.)					
Memory impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mental impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mood altered, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.2a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=15)	Male Avapritinib 25 mg (N=35)	Female Placebo (N=52)	Female Avapritinib 25 mg (N=88)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.2a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=15)	Male Avapritinib 25 mg (N=35)	Female Placebo (N=52)	Female Avapritinib 25 mg (N=88)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.2a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=15)	Male Avapritinib 25 mg (N=35)	Female Placebo (N=52)	Female Avapritinib 25 mg (N=88)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.3a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=32)	North America Avapritinib 25 mg (N=52)	Europe Placebo (N=35)	Europe Avapritinib 25 mg (N=71)	P-Value [3]
Patients with at least one Grade 3 and Higher AESI, n (%)	1 (3.1)	0	0	0	0.970
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.200		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.031 (-0.092, 0.029), 0.310		NA (NA, NA), NA	
Cognitive Effects, n (%)	1 (3.1)	0	0	0	0.970
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.200		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.031 (-0.092, 0.029), 0.310		NA (NA, NA), NA	
Mental status changes, n (%)	1 (3.1)	0	0	0	0.970
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.200		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.031 (-0.092, 0.029), 0.310		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.3a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=32)	North America Avapritinib 25 mg (N=52)	Europe Placebo (N=35)	Europe Avapritinib 25 mg (N=71)	P-Value [3]
Cognitive Effects (cont.)					
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Amnesia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.3a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=32)	North America Avapritinib 25 mg (N=52)	Europe Placebo (N=35)	Europe Avapritinib 25 mg (N=71)	P-Value [3]
Cognitive Effects (cont.)					
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.3a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=32)	North America Avapritinib 25 mg (N=52)	Europe Placebo (N=35)	Europe Avapritinib 25 mg (N=71)	P-Value [3]
Cognitive Effects (cont.)					
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.3a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=32)	North America Avapritinib 25 mg (N=52)	Europe Placebo (N=35)	Europe Avapritinib 25 mg (N=71)	P-Value [3]
Cognitive Effects (cont.)					
Memory impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mental impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mood altered, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.3a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=32)	North America Avapritinib 25 mg (N=52)	Europe Placebo (N=35)	Europe Avapritinib 25 mg (N=71)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.3a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=32)	North America Avapritinib 25 mg (N=52)	Europe Placebo (N=35)	Europe Avapritinib 25 mg (N=71)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.3a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=32)	North America Avapritinib 25 mg (N=52)	Europe Placebo (N=35)	Europe Avapritinib 25 mg (N=71)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=27)	United States Avapritinib 25 mg (N=44)	Germany Placebo (N=14)	Germany Avapritinib 25 mg (N=17)
Cognitive Effects, n (%)	1 (3.7)	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mental status changes, n (%)	1 (3.7)	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Agitation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Amnesia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=13)	France Placebo (N=5)	France Avapritinib 25 mg (N=10)
Cognitive Effects, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mental status changes, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Agitation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Amnesia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=10)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Cognitive Effects, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mental status changes, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Agitation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Amnesia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=7)	Norway Placebo (N=2)	Norway Avapritinib 25 mg (N=5)
Cognitive Effects, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mental status changes, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Agitation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Amnesia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=2)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=3)
Cognitive Effects, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mental status changes, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Agitation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Amnesia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Switzerland Placebo (N=1)	Switzerland Avapritinib 25 mg (N=2)	Sweden Placebo (N=1)	Sweden Avapritinib 25 mg (N=1)
Cognitive Effects, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mental status changes, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Agitation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Amnesia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Cognitive Effects, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Mental status changes, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Agitation, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Amnesia, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=27)	United States Avapritinib 25 mg (N=44)	Germany Placebo (N=14)	Germany Avapritinib 25 mg (N=17)
Cognitive Effects (cont.)	0	0	0	0
Cognitive disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Confusional state, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Delirium, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dementia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=13)	France Placebo (N=5)	France Avapritinib 25 mg (N=10)
Cognitive Effects (cont.)	0	0	0	0
Cognitive disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Confusional state, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Delirium, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dementia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=10)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Cognitive Effects (cont.)	0	0	0	0
Cognitive disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Confusional state, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Delirium, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dementia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=7)	Norway Placebo (N=2)	Norway Avapritinib 25 mg (N=5)
Cognitive Effects (cont.)	0	0	0	0
Cognitive disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Confusional state, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Delirium, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dementia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=2)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=3)
Cognitive Effects (cont.)	0	0	0	0
Cognitive disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Confusional state, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Delirium, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dementia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Switzerland		Sweden	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=1)	Avapritinib 25 mg (N=1)
Cognitive Effects (cont.)	0	0	0	0
Cognitive disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Confusional state, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Delirium, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dementia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Cognitive Effects (cont.)	0	0	-
Cognitive disorder, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Confusional state, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Delirium, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Dementia, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=27)	United States Avapritinib 25 mg (N=44)	Germany Placebo (N=14)	Germany Avapritinib 25 mg (N=17)
Cognitive Effects (cont.)	0	0	0	0
Disorientation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Encephalopathy, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hallucination, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Memory impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=13)	France Placebo (N=5)	France Avapritinib 25 mg (N=10)
Cognitive Effects (cont.)	0	0	0	0
Disorientation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Encephalopathy, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hallucination, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Memory impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=10)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Cognitive Effects (cont.)	0	0	0	0
Disorientation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Encephalopathy, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hallucination, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Memory impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=7)	Norway Placebo (N=2)	Norway Avapritinib 25 mg (N=5)
Cognitive Effects (cont.)	0	0	0	0
Disorientation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Encephalopathy, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hallucination, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Memory impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=2)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=3)
Cognitive Effects (cont.)	0	0	0	0
Disorientation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Encephalopathy, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hallucination, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Memory impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Switzerland Placebo (N=1)	Switzerland Avapritinib 25 mg (N=2)	Sweden Placebo (N=1)	Sweden Avapritinib 25 mg (N=1)
Cognitive Effects (cont.)	0	0	0	0
Disorientation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Encephalopathy, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hallucination, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Memory impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Cognitive Effects (cont.)	0	0	-
Disorientation, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Hallucination, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Memory impairment, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=27)	United States Avapritinib 25 mg (N=44)	Germany Placebo (N=14)	Germany Avapritinib 25 mg (N=17)
Cognitive Effects (cont.)	0	0	0	0
Mental impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mood altered, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Personality change, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Psychotic disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=13)	France Placebo (N=5)	France Avapritinib 25 mg (N=10)
Cognitive Effects (cont.)	0	0	0	0
Mental impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mood altered, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Personality change, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Psychotic disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=10)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Cognitive Effects (cont.)	0	0	0	0
Mental impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mood altered, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Personality change, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Psychotic disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=7)	Norway Placebo (N=2)	Norway Avapritinib 25 mg (N=5)
Cognitive Effects (cont.)	0	0	0	0
Mental impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mood altered, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Personality change, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Psychotic disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=2)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=3)
Cognitive Effects (cont.)	0	0	0	0
Mental impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mood altered, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Personality change, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Psychotic disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Switzerland Placebo (N=1)	Switzerland Avapritinib 25 mg (N=2)	Sweden Placebo (N=1)	Sweden Avapritinib 25 mg (N=1)
Cognitive Effects (cont.)	0	0	0	0
Mental impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mood altered, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Personality change, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Psychotic disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Cognitive Effects (cont.)	0	0	-
Mental impairment, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Mood altered, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Personality change, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=27)	United States Avapritinib 25 mg (N=44)	Germany Placebo (N=14)	Germany Avapritinib 25 mg (N=17)
Cognitive Effects (cont.)	0	0	0	0
Somnolence, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Speech disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Intracranial Bleeding, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cerebral haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=13)	France Placebo (N=5)	France Avapritinib 25 mg (N=10)
Cognitive Effects (cont.)	0	0	0	0
Somnolence, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Speech disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Intracranial Bleeding, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cerebral haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=10)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Cognitive Effects (cont.)	0	0	0	0
Somnolence, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Speech disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Intracranial Bleeding, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cerebral haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=7)	Norway Placebo (N=2)	Norway Avapritinib 25 mg (N=5)
Cognitive Effects (cont.)	0	0	0	0
Somnolence, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Speech disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Intracranial Bleeding, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cerebral haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=2)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=3)
Cognitive Effects (cont.)	0	0	0	0
Somnolence, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Speech disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Intracranial Bleeding, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cerebral haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Switzerland Placebo (N=1)	Switzerland Avapritinib 25 mg (N=2)	Sweden Placebo (N=1)	Sweden Avapritinib 25 mg (N=1)
Cognitive Effects (cont.)	0	0	0	0
Somnolence, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Speech disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Intracranial Bleeding, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cerebral haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Cognitive Effects (cont.)	0	0	-
Somnolence, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Speech disorder, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=27)	United States Avapritinib 25 mg (N=44)	Germany Placebo (N=14)	Germany Avapritinib 25 mg (N=17)
Intracranial Bleeding (cont.)	0	0	0	0
Cerebral haemorrhage, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Haemorrhage intracranial, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Subdural haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Spain		France	
	Placebo (N=3)	Avapritinib 25 mg (N=13)	Placebo (N=5)	Avapritinib 25 mg (N=10)
Intracranial Bleeding (cont.)	0	0	0	0
Cerebral haemorrhage, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Haemorrhage intracranial, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Subdural haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=10)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Intracranial Bleeding (cont.)	0	0	0	0
Cerebral haemorrhage, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Haemorrhage intracranial, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Subdural haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=7)	Norway Placebo (N=2)	Norway Avapritinib 25 mg (N=5)
Intracranial Bleeding (cont.)	0	0	0	0
Cerebral haemorrhage, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Haemorrhage intracranial, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Subdural haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=2)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=3)
Intracranial Bleeding (cont.)	0	0	0	0
Cerebral haemorrhage, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Haemorrhage intracranial, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Subdural haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Switzerland		Sweden	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=1)	Avapritinib 25 mg (N=1)
Intracranial Bleeding (cont.)	0	0	0	0
Cerebral haemorrhage, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Haemorrhage intracranial, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Subdural haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Intracranial Bleeding (cont.)	0	0	-
Cerebral haemorrhage, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.4a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=22)	Moderate Avapritinib 25 mg (N=37)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=86)	P-Value [3]
Patients with at least one Grade 3 and Higher AESI, n (%)	1 (4.5)	0	0	0	0.964
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.191		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.045 (-0.132, 0.042), 0.306		NA (NA, NA), NA	
Cognitive Effects, n (%)	1 (4.5)	0	0	0	0.964
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.191		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.045 (-0.132, 0.042), 0.306		NA (NA, NA), NA	
Mental status changes, n (%)	1 (4.5)	0	0	0	0.964
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.191		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.045 (-0.132, 0.042), 0.306		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.4a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=22)	Moderate Avapritinib 25 mg (N=37)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=86)	P-Value [3]
Cognitive Effects (cont.)					
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Amnesia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-pp-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.2.4a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=22)	Moderate Avapritinib 25 mg (N=37)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=86)	P-Value [3]
Cognitive Effects (cont.)					
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-pp-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.2.4a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=22)	Moderate Avapritinib 25 mg (N=37)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=86)	P-Value [3]
Cognitive Effects (cont.)					
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.4a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=22)	Moderate Avapritinib 25 mg (N=37)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=86)	P-Value [3]
Cognitive Effects (cont.)					
Memory impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mental impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mood altered, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.4a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=22)	Moderate Avapritinib 25 mg (N=37)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=86)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.4a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=22)	Moderate Avapritinib 25 mg (N=37)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=86)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.4a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=22)	Moderate Avapritinib 25 mg (N=37)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=86)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.5a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=13)	<20 ng/mL Avapritinib 25 mg (N=26)	>=20 ng/mL Placebo (N=54)	>=20 ng/mL Avapritinib 25 mg (N=97)	P-Value [3]
Patients with at least one Grade 3 and Higher AESI, n (%)	0	0	1 (1.9)	0	0.972
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.179	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.019 (-0.054, 0.017), 0.313	
Cognitive Effects, n (%)	0	0	1 (1.9)	0	0.972
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.179	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.019 (-0.054, 0.017), 0.313	
Mental status changes, n (%)	0	0	1 (1.9)	0	0.972
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.179	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.019 (-0.054, 0.017), 0.313	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-pp-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.2.5a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=13)	<20 ng/mL Avapritinib 25 mg (N=26)	>=20 ng/mL Placebo (N=54)	>=20 ng/mL Avapritinib 25 mg (N=97)	P-Value [3]
Cognitive Effects (cont.)					
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Amnesia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.5a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=13)	<20 ng/mL Avapritinib 25 mg (N=26)	>=20 ng/mL Placebo (N=54)	>=20 ng/mL Avapritinib 25 mg (N=97)	P-Value [3]
Cognitive Effects (cont.)					
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.5a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=13)	<20 ng/mL Avapritinib 25 mg (N=26)	>=20 ng/mL Placebo (N=54)	>=20 ng/mL Avapritinib 25 mg (N=97)	P-Value [3]
Cognitive Effects (cont.)					
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.5a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=13)	<20 ng/mL Avapritinib 25 mg (N=26)	>=20 ng/mL Placebo (N=54)	>=20 ng/mL Avapritinib 25 mg (N=97)	P-Value [3]
Cognitive Effects (cont.)					
Memory impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mental impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mood altered, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-pp-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.2.5a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=13)	<20 ng/mL Avapritinib 25 mg (N=26)	>=20 ng/mL Placebo (N=54)	>=20 ng/mL Avapritinib 25 mg (N=97)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-pp-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.2.5a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=13)	<20 ng/mL Avapritinib 25 mg (N=26)	>=20 ng/mL Placebo (N=54)	>=20 ng/mL Avapritinib 25 mg (N=97)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-pp-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.2.5a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=13)	<20 ng/mL Avapritinib 25 mg (N=26)	>=20 ng/mL Placebo (N=54)	>=20 ng/mL Avapritinib 25 mg (N=97)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.6a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=32)	 Avapritinib 25 mg (N=63)	Number of Baseline BSC >=4 Placebo (N=35)	 Avapritinib 25 mg (N=60)	P-Value [3]
Patients with at least one Grade 3 and Higher AESI, n (%)	0	0	1 (2.9)	0	0.957
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.188	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.029 (-0.084, 0.027), 0.310	
Cognitive Effects, n (%)	0	0	1 (2.9)	0	0.957
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.188	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.029 (-0.084, 0.027), 0.310	
Mental status changes, n (%)	0	0	1 (2.9)	0	0.957
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.188	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.029 (-0.084, 0.027), 0.310	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.6a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=32)	Number of Baseline BSC <4 Avapritinib 25 mg (N=63)	Number of Baseline BSC >=4 Placebo (N=35)	Number of Baseline BSC >=4 Avapritinib 25 mg (N=60)	P-Value [3]
Cognitive Effects (cont.)					
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Amnesia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.6a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=32)	Number of Baseline BSC <4 Avapritinib 25 mg (N=63)	Number of Baseline BSC >=4 Placebo (N=35)	Number of Baseline BSC >=4 Avapritinib 25 mg (N=60)	P-Value [3]
Cognitive Effects (cont.)					
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.6a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=32)	 Avapritinib 25 mg (N=63)	Number of Baseline BSC >=4 Placebo (N=35)	 Avapritinib 25 mg (N=60)	P-Value [3]
Cognitive Effects (cont.)					
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.6a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=32)	 Avapritinib 25 mg (N=63)	Number of Baseline BSC >=4 Placebo (N=35)	 Avapritinib 25 mg (N=60)	P-Value [3]
Cognitive Effects (cont.)					
Memory impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mental impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mood altered, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.6a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4		Number of Baseline BSC >=4		P-Value [3]
	Placebo (N=32)	Avapritinib 25 mg (N=63)	Placebo (N=35)	Avapritinib 25 mg (N=60)	
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.6a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=32)	 Avapritinib 25 mg (N=63)	Number of Baseline BSC >=4 Placebo (N=35)	 Avapritinib 25 mg (N=60)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.6a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=32)	 Avapritinib 25 mg (N=63)	Number of Baseline BSC >=4 Placebo (N=35)	 Avapritinib 25 mg (N=60)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.7a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=6)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=61)	No Avapritinib 25 mg (N=104)	P-Value [3]
Patients with at least one Grade 3 and Higher AESI, n (%)	0	0	1 (1.6)	0	0.980
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.190	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.016 (-0.048, 0.015), 0.313	
Cognitive Effects, n (%)	0	0	1 (1.6)	0	0.980
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.190	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.016 (-0.048, 0.015), 0.313	
Mental status changes, n (%)	0	0	1 (1.6)	0	0.980
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.190	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.016 (-0.048, 0.015), 0.313	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.7a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes		No		P-Value [3]
	Placebo (N=6)	Avapritinib 25 mg (N=19)	Placebo (N=61)	Avapritinib 25 mg (N=104)	
Cognitive Effects (cont.)					
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Amnesia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.7a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=6)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=61)	No Avapritinib 25 mg (N=104)	P-Value [3]
Cognitive Effects (cont.)					
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.7a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=6)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=61)	No Avapritinib 25 mg (N=104)	P-Value [3]
Cognitive Effects (cont.)					
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.7a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=6)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=61)	No Avapritinib 25 mg (N=104)	P-Value [3]
Cognitive Effects (cont.)					
Memory impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mental impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mood altered, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.7a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=6)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=61)	No Avapritinib 25 mg (N=104)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.7a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=6)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=61)	No Avapritinib 25 mg (N=104)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.7a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=6)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=61)	No Avapritinib 25 mg (N=104)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.8a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes		No		P-Value [3]
	Placebo (N=11)	Avapritinib 25 mg (N=25)	Placebo (N=56)	Avapritinib 25 mg (N=98)	
Patients with at least one Grade 3 and Higher AESI, n (%)	0	0	1 (1.8)	0	0.973
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.184	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.018 (-0.053, 0.017), 0.313	
Cognitive Effects, n (%)	0	0	1 (1.8)	0	0.973
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.184	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.018 (-0.053, 0.017), 0.313	
Mental status changes, n (%)	0	0	1 (1.8)	0	0.973
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.184	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.018 (-0.053, 0.017), 0.313	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-pp-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.2.8a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=25)	No Placebo (N=56)	No Avapritinib 25 mg (N=98)	P-Value [3]
Cognitive Effects (cont.)					
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Amnesia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.8a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=25)	No Placebo (N=56)	No Avapritinib 25 mg (N=98)	P-Value [3]
Cognitive Effects (cont.)					
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.8a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=25)	No Placebo (N=56)	No Avapritinib 25 mg (N=98)	P-Value [3]
Cognitive Effects (cont.)					
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.8a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=25)	No Placebo (N=56)	No Avapritinib 25 mg (N=98)	P-Value [3]
Cognitive Effects (cont.)					
Memory impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mental impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mood altered, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.8a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=25)	No Placebo (N=56)	No Avapritinib 25 mg (N=98)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.8a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=25)	No Placebo (N=56)	No Avapritinib 25 mg (N=98)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.11.3.2.8a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=25)	No Placebo (N=56)	No Avapritinib 25 mg (N=98)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

Table 35.3.1.16.1.2.1a
Summary of Oedema CMQ by Preferred Term by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Preferred Term	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	P-Value [3]
Patients with at least one Oedema CMQ, n (%)	8 (14.3)	29 (24.8)	0	5 (83.3)	0.936
Odds Ratio (95% CIs) [1], P-Value		1.977 (0.838, 4.664), 0.115		NE (NE, NE), <0.001	
Relative Risk (95% CIs) [2], P-Value		1.735 (0.849, 3.547), 0.131		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.105 (-0.015, 0.226), 0.088		0.833 (0.535, 1.000), <0.0001	
Oedema peripheral, n (%)	3 (5.4)	10 (8.5)	0	1 (16.7)	0.950
Odds Ratio (95% CIs) [1], P-Value		1.651 (0.436, 6.253), 0.456		NE (NE, NE), 0.163	
Relative Risk (95% CIs) [2], P-Value		1.595 (0.457, 5.570), 0.464		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.032 (-0.046, 0.110), 0.421		0.167 (-0.132, 0.465), 0.273	
Periorbital oedema, n (%)	2 (3.6)	6 (5.1)	0	3 (50.0)	0.938
Odds Ratio (95% CIs) [1], P-Value		1.459 (0.285, 7.471), 0.648		NE (NE, NE), 0.010	
Relative Risk (95% CIs) [2], P-Value		1.436 (0.299, 6.890), 0.651		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.016 (-0.047, 0.078), 0.628		0.500 (0.100, 0.900), 0.014	
Face oedema, n (%)	1 (1.8)	7 (6.0)	0	2 (33.3)	0.955
Odds Ratio (95% CIs) [1], P-Value		3.500 (0.420, 29.163), 0.219		NE (NE, NE), 0.041	
Relative Risk (95% CIs) [2], P-Value		3.350 (0.422, 26.577), 0.253		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.042 (-0.013, 0.097), 0.136		0.333 (-0.044, 0.711), 0.083	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.1a
Summary of Oedema CMQ by Preferred Term by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Preferred Term	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	P-Value [3]
Eyelid oedema, n (%)	1 (1.8)	5 (4.3)	0	0	0.995
Odds Ratio (95% CIs) [1], P-Value		2.455 (0.280, 21.529), 0.403		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		2.393 (0.286, 20.003), 0.421		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.025 (-0.026, 0.075), 0.334		NA (NA, NA), NA	
Fluid retention, n (%)	0	2 (1.7)	0	0	0.976
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.325		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.017 (-0.006, 0.041), 0.154		NA (NA, NA), NA	
Swelling of eyelid, n (%)	0	2 (1.7)	0	0	0.976
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.325		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.017 (-0.006, 0.041), 0.154		NA (NA, NA), NA	
Eye oedema, n (%)	1 (1.8)	1 (0.9)	0	0	0.998
Odds Ratio (95% CIs) [1], P-Value		0.474 (0.029, 7.722), 0.592		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		0.479 (0.030, 7.513), 0.600		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.009 (-0.048, 0.029), 0.635		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.1a
Summary of Oedema CMQ by Preferred Term by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Preferred Term	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	P-Value [3]
Generalised oedema, n (%)	0	1 (0.9)	0	0	0.983
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.488		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.009 (-0.008, 0.025), 0.315		NA (NA, NA), NA	
Oedema, n (%)	0	1 (0.9)	0	0	0.983
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.488		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.009 (-0.008, 0.025), 0.315		NA (NA, NA), NA	
Eye swelling, n (%)	1 (1.8)	0	0	0	0.982
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.147		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.018 (-0.053, 0.017), 0.313		NA (NA, NA), NA	
Abdominal wall oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.1a
Summary of Oedema CMQ by Preferred Term by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Preferred Term	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	P-Value [3]
Capillary leak syndrome, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Extensive interdialytic weight gain, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Gravitational oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hydraemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.1a
Summary of Oedema CMQ by Preferred Term by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Preferred Term	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	P-Value [3]
Hypervolaemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Localised oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Non-pitting oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Oedema blister, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.1a
Summary of Oedema CMQ by Preferred Term by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Preferred Term	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	P-Value [3]
Periorbital swelling, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Stoma site oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Swelling face, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Visceral oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.2a
Summary of Oedema CMQ by Preferred Term by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

	Male		Female		
Preferred Term	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	P-Value [3]
Patients with at least one Oedema CMQ, n (%)	1 (6.7)	7 (20.0)	7 (13.5)	27 (30.7)	0.864
Odds Ratio (95% CIs) [1], P-Value		3.500 (0.391, 31.314), 0.239		2.845 (1.138, 7.113), 0.022	
Relative Risk (95% CIs) [2], P-Value		3.000 (0.404, 22.303), 0.283		2.279 (1.069, 4.861), 0.033	
Risk Difference (95% CIs) [2], P-Value		0.133 (-0.050, 0.316), 0.153		0.172 (0.038, 0.306), 0.012	
Oedema peripheral, n (%)	1 (6.7)	3 (8.6)	2 (3.8)	8 (9.1)	0.656
Odds Ratio (95% CIs) [1], P-Value		1.313 (0.125, 13.744), 0.820		2.500 (0.510, 12.250), 0.244	
Relative Risk (95% CIs) [2], P-Value		1.286 (0.145, 11.383), 0.821		2.364 (0.522, 10.711), 0.265	
Risk Difference (95% CIs) [2], P-Value		0.019 (-0.138, 0.176), 0.812		0.052 (-0.027, 0.132), 0.197	
Periorbital oedema, n (%)	0	3 (8.6)	2 (3.8)	6 (6.8)	0.951
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.242		1.829 (0.355, 9.416), 0.464	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.773 (0.371, 8.463), 0.473	
Risk Difference (95% CIs) [2], P-Value		0.086 (-0.007, 0.178), 0.070		0.030 (-0.044, 0.104), 0.432	
Face oedema, n (%)	0	1 (2.9)	1 (1.9)	8 (9.1)	0.963
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.508		5.100 (0.619, 41.995), 0.095	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		4.727 (0.608, 36.735), 0.138	
Risk Difference (95% CIs) [2], P-Value		0.029 (-0.027, 0.084), 0.310		0.072 (0.001, 0.142), 0.047	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.2a
Summary of Oedema CMQ by Preferred Term by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

	Male		Female		
Preferred Term	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	P-Value [3]
Eyelid oedema, n (%)	0	2 (5.7)	1 (1.9)	3 (3.4)	0.963
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.345		1.800 (0.182, 17.769), 0.610	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.773 (0.189, 16.603), 0.616	
Risk Difference (95% CIs) [2], P-Value		0.057 (-0.020, 0.134), 0.145		0.015 (-0.038, 0.068), 0.584	
Fluid retention, n (%)	0	0	0	2 (2.3)	0.961
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.274	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.023 (-0.008, 0.054), 0.153	
Swelling of eyelid, n (%)	0	0	0	2 (2.3)	0.961
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.274	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.023 (-0.008, 0.054), 0.153	
Eye oedema, n (%)	0	0	1 (1.9)	1 (1.1)	0.997
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.586 (0.036, 9.575), 0.705	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.591 (0.038, 9.248), 0.708	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.008 (-0.051, 0.036), 0.722	

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Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.2a
Summary of Oedema CMQ by Preferred Term by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

	Male		Female		
Preferred Term	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	P-Value [3]
Generalised oedema, n (%)	0	0	0	1 (1.1)	0.973
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.440	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.011 (-0.011, 0.034), 0.315	
Oedema, n (%)	0	0	0	1 (1.1)	0.973
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.440	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.011 (-0.011, 0.034), 0.315	
Eye swelling, n (%)	0	0	1 (1.9)	0	0.967
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.192	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.019 (-0.057, 0.018), 0.313	
Abdominal wall oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.2a
Summary of Oedema CMQ by Preferred Term by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

	Male		Female		
Preferred Term	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	P-Value [3]
Capillary leak syndrome, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Extensive interdialytic weight gain, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Gravitational oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hydraemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.2a
Summary of Oedema CMQ by Preferred Term by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

	Male		Female		
Preferred Term	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	P-Value [3]
Hypervolaemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Localised oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Non-pitting oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Oedema blister, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.2a
Summary of Oedema CMQ by Preferred Term by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

	Male		Female		
Preferred Term	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	P-Value [3]
Periorbital swelling, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Stoma site oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Swelling face, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Visceral oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.3a
Summary of Oedema CMQ by Preferred Term by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Preferred Term	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	P-Value [3]
Patients with at least one Oedema CMQ, n (%)	5 (15.6)	13 (25.0)	3 (8.6)	21 (29.6)	0.300
Odds Ratio (95% CIs) [1], P-Value		1.800 (0.574, 5.640), 0.309		4.480 (1.235, 16.251), 0.015	
Relative Risk (95% CIs) [2], P-Value		1.600 (0.630, 4.066), 0.323		3.451 (1.104, 10.789), 0.033	
Risk Difference (95% CIs) [2], P-Value		0.094 (-0.079, 0.266), 0.286		0.210 (0.069, 0.351), 0.003	
Oedema peripheral, n (%)	2 (6.3)	5 (9.6)	1 (2.9)	6 (8.5)	0.630
Odds Ratio (95% CIs) [1], P-Value		1.596 (0.291, 8.758), 0.588		3.138 (0.363, 27.140), 0.275	
Relative Risk (95% CIs) [2], P-Value		1.538 (0.317, 7.466), 0.593		2.958 (0.370, 23.627), 0.306	
Risk Difference (95% CIs) [2], P-Value		0.034 (-0.082, 0.150), 0.570		0.056 (-0.029, 0.141), 0.197	
Periorbital oedema, n (%)	1 (3.1)	5 (9.6)	1 (2.9)	4 (5.6)	0.761
Odds Ratio (95% CIs) [1], P-Value		3.298 (0.367, 29.597), 0.262		2.030 (0.218, 18.874), 0.526	
Relative Risk (95% CIs) [2], P-Value		3.077 (0.376, 25.162), 0.295		1.972 (0.229, 16.989), 0.537	
Risk Difference (95% CIs) [2], P-Value		0.065 (-0.035, 0.165), 0.205		0.028 (-0.049, 0.105), 0.479	
Face oedema, n (%)	1 (3.1)	4 (7.7)	0	5 (7.0)	0.955
Odds Ratio (95% CIs) [1], P-Value		2.583 (0.276, 24.202), 0.390		NE (NE, NE), 0.108	
Relative Risk (95% CIs) [2], P-Value		2.462 (0.288, 21.060), 0.411		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.046 (-0.049, 0.140), 0.342		0.070 (0.011, 0.130), 0.020	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.3a
Summary of Oedema CMQ by Preferred Term by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Preferred Term	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	P-Value [3]
Eyelid oedema, n (%)	0	0	1 (2.9)	5 (7.0)	0.996
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		2.576 (0.289, 22.935), 0.381	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		2.465 (0.299, 20.300), 0.402	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.042 (-0.039, 0.123), 0.312	
Fluid retention, n (%)	0	1 (1.9)	0	1 (1.4)	0.999
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.430		NE (NE, NE), 0.481	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.019 (-0.018, 0.057), 0.313		0.014 (-0.013, 0.041), 0.314	
Swelling of eyelid, n (%)	0	2 (3.8)	0	0	0.965
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.262		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.038 (-0.014, 0.091), 0.149		NA (NA, NA), NA	
Eye oedema, n (%)	1 (3.1)	0	0	1 (1.4)	0.920
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.200		NE (NE, NE), 0.481	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.031 (-0.092, 0.029), 0.310		0.014 (-0.013, 0.041), 0.314	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.3a
Summary of Oedema CMQ by Preferred Term by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Preferred Term	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	P-Value [3]
Generalised oedema, n (%)	0	0	0	1 (1.4)	0.966
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.481	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.014 (-0.013, 0.041), 0.314	
Oedema, n (%)	0	0	0	1 (1.4)	0.966
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.481	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.014 (-0.013, 0.041), 0.314	
Eye swelling, n (%)	1 (3.1)	0	0	0	0.970
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.200		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.031 (-0.092, 0.029), 0.310		NA (NA, NA), NA	
Abdominal wall oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.3a
Summary of Oedema CMQ by Preferred Term by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Preferred Term	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	P-Value [3]
Capillary leak syndrome, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Extensive interdialytic weight gain, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Gravitational oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hydraemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.3a
Summary of Oedema CMQ by Preferred Term by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Preferred Term	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	P-Value [3]
Hypervolaemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Localised oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Non-pitting oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Oedema blister, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.3a
Summary of Oedema CMQ by Preferred Term by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Preferred Term	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	P-Value [3]
Periorbital swelling, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Stoma site oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Swelling face, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Visceral oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.9a
Summary of Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=27)	United States Avapritinib 25 mg (N=44)	Germany Placebo (N=14)	Germany Avapritinib 25 mg (N=17)
Patients with at least one Oedema CMQ, n (%)	4 (14.8)	9 (20.5)	1 (7.1)	4 (23.5)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema peripheral, n (%)	2 (7.4)	4 (9.1)	0	1 (5.9)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Periorbital oedema, n (%)	1 (3.7)	4 (9.1)	0	1 (5.9)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Face oedema, n (%)	0	1 (2.3)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.9a
Summary of Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Spain		France	
	Placebo (N=3)	Avapritinib 25 mg (N=13)	Placebo (N=5)	Avapritinib 25 mg (N=10)
Patients with at least one Oedema CMQ, n (%)	0	7 (53.8)	0	2 (20.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema peripheral, n (%)	0	2 (15.4)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Periorbital oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Face oedema, n (%)	0	2 (15.4)	0	1 (10.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.9a
Summary of Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom		Canada	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=8)
Patients with at least one Oedema CMQ, n (%)	0	2 (20.0)	1 (20.0)	4 (50.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema peripheral, n (%)	0	1 (10.0)	0	1 (12.5)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Periorbital oedema, n (%)	0	1 (10.0)	0	1 (12.5)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Face oedema, n (%)	0	1 (10.0)	1 (20.0)	3 (37.5)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.9a
Summary of Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands		Norway	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)
Patients with at least one Oedema CMQ, n (%)	0	1 (14.3)	0	2 (40.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema peripheral, n (%)	0	0	0	1 (20.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Periorbital oedema, n (%)	0	0	0	1 (20.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Face oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.9a
Summary of Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=2)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=3)
Patients with at least one Oedema CMQ, n (%)	0	1 (50.0)	0	1 (33.3)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema peripheral, n (%)	0	1 (50.0)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Periorbital oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Face oedema, n (%)	0	1 (50.0)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.9a
Summary of Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Switzerland		Sweden	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=1)	Avapritinib 25 mg (N=1)
Patients with at least one Oedema CMQ, n (%)	1 (100.0)	0	1 (100.0)	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema peripheral, n (%)	0	0	1 (100.0)	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Periorbital oedema, n (%)	1 (100.0)	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Face oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.9a
Summary of Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Patients with at least one Oedema CMQ, n (%)	0	1 (100.0)	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Oedema peripheral, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Periorbital oedema, n (%)	0	1 (100.0)	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Face oedema, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.9a
Summary of Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=27)	United States Avapritinib 25 mg (N=44)	Germany Placebo (N=14)	Germany Avapritinib 25 mg (N=17)
Eyelid oedema, n (%)	0	0	1 (7.1)	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Fluid retention, n (%)	0	1 (2.3)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Swelling of eyelid, n (%)	0	2 (4.5)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Eye oedema, n (%)	1 (3.7)	0	0	1 (5.9)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.9a
Summary of Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Spain		France	
	Placebo (N=3)	Avapritinib 25 mg (N=13)	Placebo (N=5)	Avapritinib 25 mg (N=10)
Eyelid oedema, n (%)	0	4 (30.8)	0	1 (10.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Fluid retention, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Swelling of eyelid, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Eye oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.9a
Summary of Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom		Canada	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=8)
Eyelid oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Fluid retention, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Swelling of eyelid, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Eye oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.9a
Summary of Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands		Norway	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)
Eyelid oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Fluid retention, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Swelling of eyelid, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Eye oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.9a
Summary of Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=2)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=3)
Eyelid oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Fluid retention, n (%)	0	0	0	1 (33.3)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Swelling of eyelid, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Eye oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.9a
Summary of Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Switzerland		Sweden	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=1)	Avapritinib 25 mg (N=1)
Eyelid oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Fluid retention, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Swelling of eyelid, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Eye oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.9a
Summary of Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Eyelid oedema, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Fluid retention, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Swelling of eyelid, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Eye oedema, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.9a
Summary of Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=27)	United States Avapritinib 25 mg (N=44)	Germany Placebo (N=14)	Germany Avapritinib 25 mg (N=17)
Generalised oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema, n (%)	0	0	0	1 (5.9)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Eye swelling, n (%)	1 (3.7)	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Abdominal wall oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.9a
Summary of Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Spain		France	
	Placebo (N=3)	Avapritinib 25 mg (N=13)	Placebo (N=5)	Avapritinib 25 mg (N=10)
Generalised oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Eye swelling, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Abdominal wall oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.9a
Summary of Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom		Canada	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=8)
Generalised oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Eye swelling, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Abdominal wall oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.9a
Summary of Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands		Norway	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)
Generalised oedema, n (%)	0	1 (14.3)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Eye swelling, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Abdominal wall oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.9a
Summary of Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=2)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=3)
Generalised oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Eye swelling, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Abdominal wall oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.9a
Summary of Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Switzerland		Sweden	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=1)	Avapritinib 25 mg (N=1)
Generalised oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Eye swelling, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Abdominal wall oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.9a
Summary of Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Generalised oedema, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Oedema, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Eye swelling, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Abdominal wall oedema, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.9a
Summary of Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=27)	United States Avapritinib 25 mg (N=44)	Germany Placebo (N=14)	Germany Avapritinib 25 mg (N=17)
Capillary leak syndrome, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Extensive interdialytic weight gain, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Gravitational oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hydraemia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.9a
Summary of Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Spain		France	
	Placebo (N=3)	Avapritinib 25 mg (N=13)	Placebo (N=5)	Avapritinib 25 mg (N=10)
Capillary leak syndrome, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Extensive interdialytic weight gain, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Gravitational oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hydraemia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.9a
Summary of Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom		Canada	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=8)
Capillary leak syndrome, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Extensive interdialytic weight gain, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Gravitational oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hydraemia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.9a
Summary of Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands		Norway	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)
Capillary leak syndrome, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Extensive interdialytic weight gain, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Gravitational oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hydraemia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.9a
Summary of Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=2)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=3)
Capillary leak syndrome, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Extensive interdialytic weight gain, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Gravitational oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hydraemia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.9a
Summary of Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Switzerland		Sweden	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=1)	Avapritinib 25 mg (N=1)
Capillary leak syndrome, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Extensive interdialytic weight gain, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Gravitational oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hydraemia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.9a
Summary of Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Capillary leak syndrome, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Extensive interdialytic weight gain, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Gravitational oedema, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Hydraemia, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.9a
Summary of Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=27)	United States Avapritinib 25 mg (N=44)	Germany Placebo (N=14)	Germany Avapritinib 25 mg (N=17)
Hypervolaemia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Localised oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Non-pitting oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema blister, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.9a
Summary of Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Spain		France	
	Placebo (N=3)	Avapritinib 25 mg (N=13)	Placebo (N=5)	Avapritinib 25 mg (N=10)
Hypervolaemia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Localised oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Non-pitting oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema blister, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.9a
Summary of Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom		Canada	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=8)
Hypervolaemia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Localised oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Non-pitting oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema blister, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.9a
Summary of Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands		Norway	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)
Hypervolaemia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Localised oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Non-pitting oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema blister, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.9a
Summary of Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium		Italy	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=0)	Avapritinib 25 mg (N=3)
Hypervolaemia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Localised oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Non-pitting oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema blister, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.9a
Summary of Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Switzerland		Sweden	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=1)	Avapritinib 25 mg (N=1)
Hypervolaemia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Localised oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Non-pitting oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema blister, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.9a
Summary of Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Hypervolaemia, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Localised oedema, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Non-pitting oedema, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Oedema blister, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.9a
Summary of Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=27)	United States Avapritinib 25 mg (N=44)	Germany Placebo (N=14)	Germany Avapritinib 25 mg (N=17)
Periorbital swelling, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Stoma site oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Swelling face, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Visceral oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.9a
Summary of Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Spain		France	
	Placebo (N=3)	Avapritinib 25 mg (N=13)	Placebo (N=5)	Avapritinib 25 mg (N=10)
Periorbital swelling, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Stoma site oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Swelling face, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Visceral oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.9a
Summary of Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom		Canada	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=8)
Periorbital swelling, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Stoma site oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Swelling face, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Visceral oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.9a
Summary of Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=7)	Norway Placebo (N=2)	Norway Avapritinib 25 mg (N=5)
Periorbital swelling, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Stoma site oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Swelling face, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Visceral oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.9a
Summary of Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium		Italy	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=0)	Avapritinib 25 mg (N=3)
Periorbital swelling, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Stoma site oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Swelling face, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Visceral oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.9a
Summary of Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Switzerland		Sweden	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=1)	Avapritinib 25 mg (N=1)
Periorbital swelling, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Stoma site oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Swelling face, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Visceral oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.9a
Summary of Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Periorbital swelling, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Stoma site oedema, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Swelling face, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Visceral oedema, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.4a
Summary of Oedema CMQ by Preferred Term by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Preferred Term	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	P-Value [3]
Patients with at least one Oedema CMQ, n (%)	2 (9.1)	8 (21.6)	6 (13.3)	26 (30.2)	0.983
Odds Ratio (95% CIs) [1], P-Value		2.759 (0.529, 14.377), 0.215		2.817 (1.062, 7.467), 0.033	
Relative Risk (95% CIs) [2], P-Value		2.378 (0.554, 10.209), 0.244		2.267 (1.008, 5.103), 0.048	
Risk Difference (95% CIs) [2], P-Value		0.125 (-0.054, 0.304), 0.170		0.169 (0.030, 0.308), 0.017	
Oedema peripheral, n (%)	1 (4.5)	4 (10.8)	2 (4.4)	7 (8.1)	0.838
Odds Ratio (95% CIs) [1], P-Value		2.545 (0.266, 24.359), 0.403		1.905 (0.379, 9.576), 0.427	
Relative Risk (95% CIs) [2], P-Value		2.378 (0.284, 19.950), 0.425		1.831 (0.397, 8.454), 0.438	
Risk Difference (95% CIs) [2], P-Value		0.063 (-0.070, 0.195), 0.354		0.037 (-0.047, 0.120), 0.386	
Periorbital oedema, n (%)	1 (4.5)	1 (2.7)	1 (2.2)	8 (9.3)	0.255
Odds Ratio (95% CIs) [1], P-Value		0.583 (0.035, 9.822), 0.705		4.513 (0.546, 37.277), 0.128	
Relative Risk (95% CIs) [2], P-Value		0.595 (0.039, 9.036), 0.708		4.186 (0.540, 32.430), 0.170	
Risk Difference (95% CIs) [2], P-Value		-0.018 (-0.120, 0.083), 0.722		0.071 (-0.004, 0.146), 0.064	
Face oedema, n (%)	0	3 (8.1)	1 (2.2)	6 (7.0)	0.964
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.170		3.300 (0.385, 28.294), 0.251	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		3.140 (0.390, 25.283), 0.282	
Risk Difference (95% CIs) [2], P-Value		0.081 (-0.007, 0.169), 0.071		0.048 (-0.021, 0.116), 0.177	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.4a
Summary of Oedema CMQ by Preferred Term by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Preferred Term	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	P-Value [3]
Eyelid oedema, n (%)	0	1 (2.7)	1 (2.2)	4 (4.7)	0.960
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.437		2.146 (0.233, 19.796), 0.491	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		2.093 (0.241, 18.175), 0.503	
Risk Difference (95% CIs) [2], P-Value		0.027 (-0.025, 0.079), 0.311		0.024 (-0.038, 0.086), 0.442	
Fluid retention, n (%)	0	0	0	2 (2.3)	0.971
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.303	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.023 (-0.009, 0.055), 0.152	
Swelling of eyelid, n (%)	0	0	0	2 (2.3)	0.971
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.303	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.023 (-0.009, 0.055), 0.152	
Eye oedema, n (%)	0	1 (2.7)	1 (2.2)	0	0.925
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.437		NE (NE, NE), 0.165	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.027 (-0.025, 0.079), 0.311		-0.022 (-0.065, 0.021), 0.312	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.4a
Summary of Oedema CMQ by Preferred Term by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Preferred Term	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	P-Value [3]
Generalised oedema, n (%)	0	0	0	1 (1.2)	0.970
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.468	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.012 (-0.011, 0.034), 0.314	
Oedema, n (%)	0	0	0	1 (1.2)	0.970
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.468	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.012 (-0.011, 0.034), 0.314	
Eye swelling, n (%)	0	0	1 (2.2)	0	0.965
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.165	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.022 (-0.065, 0.021), 0.312	
Abdominal wall oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.4a
Summary of Oedema CMQ by Preferred Term by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Preferred Term	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	P-Value [3]
Capillary leak syndrome, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Extensive interdialytic weight gain, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Gravitational oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hydraemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.4a
Summary of Oedema CMQ by Preferred Term by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Preferred Term	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	P-Value [3]
Hypervolaemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Localised oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Non-pitting oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Oedema blister, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.4a
Summary of Oedema CMQ by Preferred Term by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Preferred Term	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	P-Value [3]
Periorbital swelling, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Stoma site oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Swelling face, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Visceral oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

Table 35.3.1.16.1.2.5a
Summary of Oedema CMQ by Preferred Term by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Preferred Term	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	P-Value [3]
Patients with at least one Oedema CMQ, n (%)	2 (15.4)	6 (23.1)	6 (11.1)	28 (28.9)	0.508
Odds Ratio (95% CIs) [1], P-Value		1.650 (0.283, 9.603), 0.575		3.246 (1.249, 8.441), 0.012	
Relative Risk (95% CIs) [2], P-Value		1.500 (0.350, 6.428), 0.585		2.598 (1.148, 5.878), 0.022	
Risk Difference (95% CIs) [2], P-Value		0.077 (-0.177, 0.331), 0.553		0.178 (0.054, 0.301), 0.005	
Oedema peripheral, n (%)	1 (7.7)	2 (7.7)	2 (3.7)	9 (9.3)	0.516
Odds Ratio (95% CIs) [1], P-Value		1.000 (0.082, 12.164), >0.999		2.659 (0.553, 12.782), 0.206	
Relative Risk (95% CIs) [2], P-Value		1.000 (0.100, 10.037), >0.999		2.505 (0.561, 11.178), 0.229	
Risk Difference (95% CIs) [2], P-Value		0.000 (-0.177, 0.177), >0.999		0.056 (-0.021, 0.132), 0.154	
Periorbital oedema, n (%)	0	1 (3.8)	2 (3.7)	8 (8.2)	0.973
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.474		2.337 (0.478, 11.424), 0.282	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		2.227 (0.490, 10.114), 0.300	
Risk Difference (95% CIs) [2], P-Value		0.038 (-0.035, 0.112), 0.308		0.045 (-0.029, 0.120), 0.231	
Face oedema, n (%)	0	3 (11.5)	1 (1.9)	6 (6.2)	0.958
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.202		3.495 (0.410, 29.818), 0.225	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		3.340 (0.413, 27.024), 0.258	
Risk Difference (95% CIs) [2], P-Value		0.115 (-0.007, 0.238), 0.066		0.043 (-0.017, 0.103), 0.156	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.5a
Summary of Oedema CMQ by Preferred Term by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Preferred Term	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	P-Value [3]
Eyelid oedema, n (%)	0	0	1 (1.9)	5 (5.2)	0.997
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		2.880 (0.328, 25.315), 0.319	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		2.784 (0.334, 23.215), 0.344	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.033 (-0.024, 0.090), 0.255	
Fluid retention, n (%)	0	1 (3.8)	0	1 (1.0)	0.996
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.474		NE (NE, NE), 0.454	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.038 (-0.035, 0.112), 0.308		0.010 (-0.010, 0.030), 0.315	
Swelling of eyelid, n (%)	0	0	0	2 (2.1)	0.976
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.288	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.021 (-0.008, 0.049), 0.153	
Eye oedema, n (%)	0	0	1 (1.9)	1 (1.0)	0.998
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.552 (0.034, 9.007), 0.672	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.557 (0.036, 8.724), 0.677	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.008 (-0.049, 0.033), 0.696	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.5a
Summary of Oedema CMQ by Preferred Term by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Preferred Term	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	P-Value [3]
Generalised oedema, n (%)	0	0	0	1 (1.0)	0.975
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.454	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.010 (-0.010, 0.030), 0.315	
Oedema, n (%)	0	1 (3.8)	0	0	0.963
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.474		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.038 (-0.035, 0.112), 0.308		NA (NA, NA), NA	
Eye swelling, n (%)	1 (7.7)	0	0	0	0.971
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.152		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.077 (-0.222, 0.068), 0.298		NA (NA, NA), NA	
Abdominal wall oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.5a
Summary of Oedema CMQ by Preferred Term by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Preferred Term	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	P-Value [3]
Capillary leak syndrome, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Extensive interdialytic weight gain, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Gravitational oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hydraemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.5a
Summary of Oedema CMQ by Preferred Term by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Preferred Term	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	P-Value [3]
Hypervolaemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Localised oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Non-pitting oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Oedema blister, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.5a
Summary of Oedema CMQ by Preferred Term by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Preferred Term	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	P-Value [3]
Periorbital swelling, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Stoma site oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Swelling face, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Visceral oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.6a
Summary of Oedema CMQ by Preferred Term by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Preferred Term	Placebo (N=32)	Avapritinib 25 mg (N=63)	Placebo (N=35)	Avapritinib 25 mg (N=60)	P-Value [3]
Patients with at least one Oedema CMQ, n (%)	2 (6.3)	16 (25.4)	6 (17.1)	18 (30.0)	0.341
Odds Ratio (95% CIs) [1], P-Value		5.106 (1.095, 23.811), 0.024		2.071 (0.734, 5.849), 0.164	
Relative Risk (95% CIs) [2], P-Value		4.063 (0.995, 16.595), 0.051		1.750 (0.767, 3.991), 0.183	
Risk Difference (95% CIs) [2], P-Value		0.191 (0.055, 0.328), 0.006		0.129 (-0.042, 0.299), 0.139	
Oedema peripheral, n (%)	1 (3.1)	5 (7.9)	2 (5.7)	6 (10.0)	0.788
Odds Ratio (95% CIs) [1], P-Value		2.672 (0.299, 23.899), 0.362		1.833 (0.349, 9.622), 0.468	
Relative Risk (95% CIs) [2], P-Value		2.540 (0.310, 20.832), 0.385		1.750 (0.373, 8.204), 0.478	
Risk Difference (95% CIs) [2], P-Value		0.048 (-0.042, 0.138), 0.294		0.043 (-0.065, 0.151), 0.437	
Periorbital oedema, n (%)	0	2 (3.2)	2 (5.7)	7 (11.7)	0.958
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.308		2.179 (0.427, 11.128), 0.339	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		2.042 (0.449, 9.290), 0.356	
Risk Difference (95% CIs) [2], P-Value		0.032 (-0.012, 0.075), 0.151		0.060 (-0.052, 0.171), 0.297	
Face oedema, n (%)	0	4 (6.3)	1 (2.9)	5 (8.3)	0.958
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.145		3.091 (0.346, 27.596), 0.290	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		2.917 (0.355, 23.966), 0.319	
Risk Difference (95% CIs) [2], P-Value		0.063 (0.003, 0.124), 0.039		0.055 (-0.034, 0.144), 0.228	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.6a
Summary of Oedema CMQ by Preferred Term by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Preferred Term	Placebo (N=32)	Avapritinib 25 mg (N=63)	Placebo (N=35)	Avapritinib 25 mg (N=60)	P-Value [3]
Eyelid oedema, n (%)	1 (3.1)	1 (1.6)	0	4 (6.7)	0.936
Odds Ratio (95% CIs) [1], P-Value		0.500 (0.030, 8.265), 0.622		NE (NE, NE), 0.119	
Relative Risk (95% CIs) [2], P-Value		0.508 (0.033, 7.858), 0.628		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.015 (-0.083, 0.052), 0.656		0.067 (0.004, 0.130), 0.038	
Fluid retention, n (%)	0	2 (3.2)	0	0	0.967
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.308		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.032 (-0.012, 0.075), 0.151		NA (NA, NA), NA	
Swelling of eyelid, n (%)	0	1 (1.6)	0	1 (1.7)	>0.999
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.474		NE (NE, NE), 0.443	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.016 (-0.015, 0.047), 0.313		0.017 (-0.016, 0.049), 0.313	
Eye oedema, n (%)	0	1 (1.6)	1 (2.9)	0	0.920
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.474		NE (NE, NE), 0.188	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.016 (-0.015, 0.047), 0.313		-0.029 (-0.084, 0.027), 0.310	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.6a
Summary of Oedema CMQ by Preferred Term by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Preferred Term	Placebo (N=32)	Avapritinib 25 mg (N=63)	Placebo (N=35)	Avapritinib 25 mg (N=60)	P-Value [3]
Generalised oedema, n (%)	0	1 (1.6)	0	0	0.965
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.474		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.016 (-0.015, 0.047), 0.313		NA (NA, NA), NA	
Oedema, n (%)	0	1 (1.6)	0	0	0.965
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.474		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.016 (-0.015, 0.047), 0.313		NA (NA, NA), NA	
Eye swelling, n (%)	0	0	1 (2.9)	0	0.957
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.188	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.029 (-0.084, 0.027), 0.310	
Abdominal wall oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.6a
Summary of Oedema CMQ by Preferred Term by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Preferred Term	Placebo (N=32)	Avapritinib 25 mg (N=63)	Placebo (N=35)	Avapritinib 25 mg (N=60)	P-Value [3]
Capillary leak syndrome, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Extensive interdialytic weight gain, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Gravitational oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hydraemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.6a
Summary of Oedema CMQ by Preferred Term by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Preferred Term	Placebo (N=32)	Avapritinib 25 mg (N=63)	Placebo (N=35)	Avapritinib 25 mg (N=60)	P-Value [3]
Hypervolaemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Localised oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Non-pitting oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Oedema blister, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.6a
Summary of Oedema CMQ by Preferred Term by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Preferred Term	Placebo (N=32)	Avapritinib 25 mg (N=63)	Placebo (N=35)	Avapritinib 25 mg (N=60)	P-Value [3]
Periorbital swelling, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Stoma site oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Swelling face, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Visceral oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.7a
Summary of Oedema CMQ by Preferred Term by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Preferred Term	Placebo (N=6)	Avapritinib 25 mg (N=19)	Placebo (N=61)	Avapritinib 25 mg (N=104)	P-Value [3]
Patients with at least one Oedema CMQ, n (%)	0	5 (26.3)	8 (13.1)	29 (27.9)	0.963
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.160		2.562 (1.086, 6.042), 0.028	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		2.126 (1.039, 4.351), 0.039	
Risk Difference (95% CIs) [2], P-Value		0.263 (0.065, 0.461), 0.009		0.148 (0.027, 0.269), 0.017	
Oedema peripheral, n (%)	0	2 (10.5)	3 (4.9)	9 (8.7)	0.965
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.407		1.832 (0.476, 7.043), 0.372	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.760 (0.495, 6.252), 0.382	
Risk Difference (95% CIs) [2], P-Value		0.105 (-0.033, 0.243), 0.135		0.037 (-0.039, 0.114), 0.339	
Periorbital oedema, n (%)	0	1 (5.3)	2 (3.3)	8 (7.7)	0.958
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.566		2.458 (0.505, 11.972), 0.251	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		2.346 (0.515, 10.694), 0.271	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		0.044 (-0.024, 0.112), 0.203	
Face oedema, n (%)	0	2 (10.5)	1 (1.6)	7 (6.7)	0.959
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.407		4.330 (0.520, 36.068), 0.142	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		4.106 (0.517, 32.580), 0.181	
Risk Difference (95% CIs) [2], P-Value		0.105 (-0.033, 0.243), 0.135		0.051 (-0.007, 0.109), 0.084	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.7a
Summary of Oedema CMQ by Preferred Term by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Preferred Term	Placebo (N=6)	Avapritinib 25 mg (N=19)	Placebo (N=61)	Avapritinib 25 mg (N=104)	P-Value [3]
Eyelid oedema, n (%)	0	0	1 (1.6)	5 (4.8)	0.994
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		3.030 (0.346, 26.563), 0.294	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		2.933 (0.351, 24.522), 0.321	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.032 (-0.020, 0.084), 0.233	
Fluid retention, n (%)	0	0	0	2 (1.9)	0.973
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.276	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.019 (-0.007, 0.046), 0.153	
Swelling of eyelid, n (%)	0	1 (5.3)	0	1 (1.0)	0.998
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.566		NE (NE, NE), 0.442	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		0.010 (-0.009, 0.028), 0.315	
Eye oedema, n (%)	0	0	1 (1.6)	1 (1.0)	0.998
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.583 (0.036, 9.484), 0.701	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.587 (0.037, 9.209), 0.704	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.007 (-0.044, 0.030), 0.719	

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Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.7a
Summary of Oedema CMQ by Preferred Term by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Preferred Term	Placebo (N=6)	Avapritinib 25 mg (N=19)	Placebo (N=61)	Avapritinib 25 mg (N=104)	P-Value [3]
Generalised oedema, n (%)	0	0	0	1 (1.0)	0.981
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.442	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.010 (-0.009, 0.028), 0.315	
Oedema, n (%)	0	1 (5.3)	0	0	0.960
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.566		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		NA (NA, NA), NA	
Eye swelling, n (%)	0	0	1 (1.6)	0	0.980
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.190	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.016 (-0.048, 0.015), 0.313	
Abdominal wall oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.7a
Summary of Oedema CMQ by Preferred Term by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Preferred Term	Placebo (N=6)	Avapritinib 25 mg (N=19)	Placebo (N=61)	Avapritinib 25 mg (N=104)	P-Value [3]
Capillary leak syndrome, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Extensive interdialytic weight gain, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Gravitational oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hydraemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.7a
Summary of Oedema CMQ by Preferred Term by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Preferred Term	Placebo (N=6)	Avapritinib 25 mg (N=19)	Placebo (N=61)	Avapritinib 25 mg (N=104)	P-Value [3]
Hypervolaemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Localised oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Non-pitting oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Oedema blister, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.7a
Summary of Oedema CMQ by Preferred Term by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Preferred Term	Placebo (N=6)	Avapritinib 25 mg (N=19)	Placebo (N=61)	Avapritinib 25 mg (N=104)	P-Value [3]
Periorbital swelling, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Stoma site oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Swelling face, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Visceral oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.8a
Summary of Oedema CMQ by Preferred Term by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Preferred Term	Placebo (N=11)	Avapritinib 25 mg (N=25)	Placebo (N=56)	Avapritinib 25 mg (N=98)	P-Value [3]
Patients with at least one Oedema CMQ, n (%)	2 (18.2)	6 (24.0)	6 (10.7)	28 (28.6)	0.409
Odds Ratio (95% CIs) [1], P-Value		1.421 (0.238, 8.478), 0.699		3.333 (1.285, 8.649), 0.010	
Relative Risk (95% CIs) [2], P-Value		1.320 (0.314, 5.541), 0.704		2.667 (1.176, 6.044), 0.019	
Risk Difference (95% CIs) [2], P-Value		0.058 (-0.225, 0.341), 0.687		0.179 (0.058, 0.299), 0.004	
Oedema peripheral, n (%)	0	2 (8.0)	3 (5.4)	9 (9.2)	0.954
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.334		1.787 (0.463, 6.893), 0.394	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.714 (0.484, 6.072), 0.404	
Risk Difference (95% CIs) [2], P-Value		0.080 (-0.026, 0.186), 0.140		0.038 (-0.044, 0.120), 0.361	
Periorbital oedema, n (%)	0	1 (4.0)	2 (3.6)	8 (8.2)	0.963
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.501		2.400 (0.491, 11.720), 0.266	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		2.286 (0.503, 10.391), 0.285	
Risk Difference (95% CIs) [2], P-Value		0.040 (-0.037, 0.117), 0.307		0.046 (-0.027, 0.119), 0.216	
Face oedema, n (%)	0	4 (16.0)	1 (1.8)	5 (5.1)	0.959
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.159		2.957 (0.337, 25.970), 0.306	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		2.857 (0.342, 23.846), 0.332	
Risk Difference (95% CIs) [2], P-Value		0.160 (0.016, 0.304), 0.029		0.033 (-0.023, 0.089), 0.243	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.8a
Summary of Oedema CMQ by Preferred Term by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Preferred Term	Placebo (N=11)	Avapritinib 25 mg (N=25)	Placebo (N=56)	Avapritinib 25 mg (N=98)	P-Value [3]
Eyelid oedema, n (%)	0	0	1 (1.8)	5 (5.1)	0.995
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		2.957 (0.337, 25.970), 0.306	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		2.857 (0.342, 23.846), 0.332	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.033 (-0.023, 0.089), 0.243	
Fluid retention, n (%)	0	1 (4.0)	0	1 (1.0)	0.998
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.501		NE (NE, NE), 0.448	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.040 (-0.037, 0.117), 0.307		0.010 (-0.010, 0.030), 0.315	
Swelling of eyelid, n (%)	0	0	0	2 (2.0)	0.966
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.282	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.020 (-0.008, 0.048), 0.153	
Eye oedema, n (%)	1 (9.1)	0	0	1 (1.0)	0.900
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.126		NE (NE, NE), 0.448	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.091 (-0.261, 0.079), 0.294		0.010 (-0.010, 0.030), 0.315	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.8a
Summary of Oedema CMQ by Preferred Term by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Preferred Term	Placebo (N=11)	Avapritinib 25 mg (N=25)	Placebo (N=56)	Avapritinib 25 mg (N=98)	P-Value [3]
Generalised oedema, n (%)	0	0	0	1 (1.0)	0.976
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.448	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.010 (-0.010, 0.030), 0.315	
Oedema, n (%)	0	0	0	1 (1.0)	0.976
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.448	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.010 (-0.010, 0.030), 0.315	
Eye swelling, n (%)	1 (9.1)	0	0	0	0.963
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.126		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.091 (-0.261, 0.079), 0.294		NA (NA, NA), NA	
Abdominal wall oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.8a
Summary of Oedema CMQ by Preferred Term by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Preferred Term	Placebo (N=11)	Avapritinib 25 mg (N=25)	Placebo (N=56)	Avapritinib 25 mg (N=98)	P-Value [3]
Capillary leak syndrome, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Extensive interdialytic weight gain, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Gravitational oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hydraemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.8a
Summary of Oedema CMQ by Preferred Term by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Preferred Term	Placebo (N=11)	Avapritinib 25 mg (N=25)	Placebo (N=56)	Avapritinib 25 mg (N=98)	P-Value [3]
Hypervolaemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Localised oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Non-pitting oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Oedema blister, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.1.2.8a
Summary of Oedema CMQ by Preferred Term by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Preferred Term	Placebo (N=11)	Avapritinib 25 mg (N=25)	Placebo (N=56)	Avapritinib 25 mg (N=98)	P-Value [3]
Periorbital swelling, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Stoma site oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Swelling face, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Visceral oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.3.2.1a
Summary of Serious Oedema CMQ by Preferred Term by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.3.2.2a
Summary of Serious Oedema CMQ by Preferred Term by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.3.2.3a
Summary of Serious Oedema CMQ by Preferred Term by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.3.2.9a
Summary of Serious Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sae-cmq-pp-country-a.sas Date: 11:52/20JUL2023

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Table 35.3.1.16.3.2.4a
Summary of Serious Oedema CMQ by Preferred Term by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.3.2.5a
Summary of Serious Oedema CMQ by Preferred Term by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.3.2.6a
Summary of Serious Oedema CMQ by Preferred Term by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.3.2.7a
Summary of Serious Oedema CMQ by Preferred Term by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.3.2.8a
Summary of Serious Oedema CMQ by Preferred Term by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.1a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Preferred Term	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	P-Value [3]
Patients with at least one Grade 1 and 2 Oedema CMQ, n (%)	8 (14.3)	29 (24.8)	0	5 (83.3)	0.936
Odds Ratio (95% CIs) [1], P-Value		1.977 (0.838, 4.664), 0.115		NE (NE, NE), <0.001	
Relative Risk (95% CIs) [2], P-Value		1.735 (0.849, 3.547), 0.131		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.105 (-0.015, 0.226), 0.088		0.833 (0.535, 1.000), <0.0001	
Oedema peripheral, n (%)	3 (5.4)	10 (8.5)	0	1 (16.7)	0.950
Odds Ratio (95% CIs) [1], P-Value		1.651 (0.436, 6.253), 0.456		NE (NE, NE), 0.163	
Relative Risk (95% CIs) [2], P-Value		1.595 (0.457, 5.570), 0.464		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.032 (-0.046, 0.110), 0.421		0.167 (-0.132, 0.465), 0.273	
Periorbital oedema, n (%)	2 (3.6)	6 (5.1)	0	3 (50.0)	0.938
Odds Ratio (95% CIs) [1], P-Value		1.459 (0.285, 7.471), 0.648		NE (NE, NE), 0.010	
Relative Risk (95% CIs) [2], P-Value		1.436 (0.299, 6.890), 0.651		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.016 (-0.047, 0.078), 0.628		0.500 (0.100, 0.900), 0.014	
Face oedema, n (%)	1 (1.8)	7 (6.0)	0	2 (33.3)	0.955
Odds Ratio (95% CIs) [1], P-Value		3.500 (0.420, 29.163), 0.219		NE (NE, NE), 0.041	
Relative Risk (95% CIs) [2], P-Value		3.350 (0.422, 26.577), 0.253		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.042 (-0.013, 0.097), 0.136		0.333 (-0.044, 0.711), 0.083	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.1a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Preferred Term	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	P-Value [3]
Eyelid oedema, n (%)	1 (1.8)	5 (4.3)	0	0	0.995
Odds Ratio (95% CIs) [1], P-Value		2.455 (0.280, 21.529), 0.403		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		2.393 (0.286, 20.003), 0.421		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.025 (-0.026, 0.075), 0.334		NA (NA, NA), NA	
Fluid retention, n (%)	0	2 (1.7)	0	0	0.976
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.325		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.017 (-0.006, 0.041), 0.154		NA (NA, NA), NA	
Swelling of eyelid, n (%)	0	2 (1.7)	0	0	0.976
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.325		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.017 (-0.006, 0.041), 0.154		NA (NA, NA), NA	
Eye oedema, n (%)	1 (1.8)	1 (0.9)	0	0	0.998
Odds Ratio (95% CIs) [1], P-Value		0.474 (0.029, 7.722), 0.592		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		0.479 (0.030, 7.513), 0.600		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.009 (-0.048, 0.029), 0.635		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.1a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Preferred Term	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	P-Value [3]
Generalised oedema, n (%)	0	1 (0.9)	0	0	0.983
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.488		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.009 (-0.008, 0.025), 0.315		NA (NA, NA), NA	
Oedema, n (%)	0	1 (0.9)	0	0	0.983
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.488		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.009 (-0.008, 0.025), 0.315		NA (NA, NA), NA	
Eye swelling, n (%)	1 (1.8)	0	0	0	0.982
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.147		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.018 (-0.053, 0.017), 0.313		NA (NA, NA), NA	
Abdominal wall oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.1a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Preferred Term	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	P-Value [3]
Capillary leak syndrome, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Extensive interdialytic weight gain, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Gravitational oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hydraemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.1a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Preferred Term	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	P-Value [3]
Hypervolaemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Localised oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Non-pitting oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Oedema blister, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.1a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Preferred Term	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	P-Value [3]
Periorbital swelling, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Stoma site oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Swelling face, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Visceral oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.2a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

	Male		Female		
Preferred Term	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	P-Value [3]
Patients with at least one Grade 1 and 2 Oedema CMQ, n (%)	1 (6.7)	7 (20.0)	7 (13.5)	27 (30.7)	0.864
Odds Ratio (95% CIs) [1], P-Value		3.500 (0.391, 31.314), 0.239		2.845 (1.138, 7.113), 0.022	
Relative Risk (95% CIs) [2], P-Value		3.000 (0.404, 22.303), 0.283		2.279 (1.069, 4.861), 0.033	
Risk Difference (95% CIs) [2], P-Value		0.133 (-0.050, 0.316), 0.153		0.172 (0.038, 0.306), 0.012	
Oedema peripheral, n (%)	1 (6.7)	3 (8.6)	2 (3.8)	8 (9.1)	0.656
Odds Ratio (95% CIs) [1], P-Value		1.313 (0.125, 13.744), 0.820		2.500 (0.510, 12.250), 0.244	
Relative Risk (95% CIs) [2], P-Value		1.286 (0.145, 11.383), 0.821		2.364 (0.522, 10.711), 0.265	
Risk Difference (95% CIs) [2], P-Value		0.019 (-0.138, 0.176), 0.812		0.052 (-0.027, 0.132), 0.197	
Periorbital oedema, n (%)	0	3 (8.6)	2 (3.8)	6 (6.8)	0.951
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.242		1.829 (0.355, 9.416), 0.464	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.773 (0.371, 8.463), 0.473	
Risk Difference (95% CIs) [2], P-Value		0.086 (-0.007, 0.178), 0.070		0.030 (-0.044, 0.104), 0.432	
Face oedema, n (%)	0	1 (2.9)	1 (1.9)	8 (9.1)	0.963
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.508		5.100 (0.619, 41.995), 0.095	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		4.727 (0.608, 36.735), 0.138	
Risk Difference (95% CIs) [2], P-Value		0.029 (-0.027, 0.084), 0.310		0.072 (0.001, 0.142), 0.047	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.2a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

	Male		Female		
Preferred Term	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	P-Value [3]
Eyelid oedema, n (%)	0	2 (5.7)	1 (1.9)	3 (3.4)	0.963
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.345		1.800 (0.182, 17.769), 0.610	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.773 (0.189, 16.603), 0.616	
Risk Difference (95% CIs) [2], P-Value		0.057 (-0.020, 0.134), 0.145		0.015 (-0.038, 0.068), 0.584	
Fluid retention, n (%)	0	0	0	2 (2.3)	0.961
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.274	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.023 (-0.008, 0.054), 0.153	
Swelling of eyelid, n (%)	0	0	0	2 (2.3)	0.961
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.274	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.023 (-0.008, 0.054), 0.153	
Eye oedema, n (%)	0	0	1 (1.9)	1 (1.1)	0.997
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.586 (0.036, 9.575), 0.705	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.591 (0.038, 9.248), 0.708	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.008 (-0.051, 0.036), 0.722	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.2a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

	Male		Female		
Preferred Term	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	P-Value [3]
Generalised oedema, n (%)	0	0	0	1 (1.1)	0.973
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.440	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.011 (-0.011, 0.034), 0.315	
Oedema, n (%)	0	0	0	1 (1.1)	0.973
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.440	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.011 (-0.011, 0.034), 0.315	
Eye swelling, n (%)	0	0	1 (1.9)	0	0.967
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.192	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.019 (-0.057, 0.018), 0.313	
Abdominal wall oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.2a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

	Male		Female		
Preferred Term	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	P-Value [3]
Capillary leak syndrome, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Extensive interdialytic weight gain, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Gravitational oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hydraemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.2a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

	Male		Female		
Preferred Term	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	P-Value [3]
Hypervolaemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Localised oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Non-pitting oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Oedema blister, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.2a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

	Male		Female		
Preferred Term	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	P-Value [3]
Periorbital swelling, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Stoma site oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Swelling face, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Visceral oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.3a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Preferred Term	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	P-Value [3]
Patients with at least one Grade 1 and 2 Oedema CMQ, n (%)	5 (15.6)	13 (25.0)	3 (8.6)	21 (29.6)	0.300
Odds Ratio (95% CIs) [1], P-Value		1.800 (0.574, 5.640), 0.309		4.480 (1.235, 16.251), 0.015	
Relative Risk (95% CIs) [2], P-Value		1.600 (0.630, 4.066), 0.323		3.451 (1.104, 10.789), 0.033	
Risk Difference (95% CIs) [2], P-Value		0.094 (-0.079, 0.266), 0.286		0.210 (0.069, 0.351), 0.003	
Oedema peripheral, n (%)	2 (6.3)	5 (9.6)	1 (2.9)	6 (8.5)	0.630
Odds Ratio (95% CIs) [1], P-Value		1.596 (0.291, 8.758), 0.588		3.138 (0.363, 27.140), 0.275	
Relative Risk (95% CIs) [2], P-Value		1.538 (0.317, 7.466), 0.593		2.958 (0.370, 23.627), 0.306	
Risk Difference (95% CIs) [2], P-Value		0.034 (-0.082, 0.150), 0.570		0.056 (-0.029, 0.141), 0.197	
Periorbital oedema, n (%)	1 (3.1)	5 (9.6)	1 (2.9)	4 (5.6)	0.761
Odds Ratio (95% CIs) [1], P-Value		3.298 (0.367, 29.597), 0.262		2.030 (0.218, 18.874), 0.526	
Relative Risk (95% CIs) [2], P-Value		3.077 (0.376, 25.162), 0.295		1.972 (0.229, 16.989), 0.537	
Risk Difference (95% CIs) [2], P-Value		0.065 (-0.035, 0.165), 0.205		0.028 (-0.049, 0.105), 0.479	
Face oedema, n (%)	1 (3.1)	4 (7.7)	0	5 (7.0)	0.955
Odds Ratio (95% CIs) [1], P-Value		2.583 (0.276, 24.202), 0.390		NE (NE, NE), 0.108	
Relative Risk (95% CIs) [2], P-Value		2.462 (0.288, 21.060), 0.411		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.046 (-0.049, 0.140), 0.342		0.070 (0.011, 0.130), 0.020	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.3a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Preferred Term	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	P-Value [3]
Eyelid oedema, n (%)	0	0	1 (2.9)	5 (7.0)	0.996
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		2.576 (0.289, 22.935), 0.381	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		2.465 (0.299, 20.300), 0.402	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.042 (-0.039, 0.123), 0.312	
Fluid retention, n (%)	0	1 (1.9)	0	1 (1.4)	0.999
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.430		NE (NE, NE), 0.481	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.019 (-0.018, 0.057), 0.313		0.014 (-0.013, 0.041), 0.314	
Swelling of eyelid, n (%)	0	2 (3.8)	0	0	0.965
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.262		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.038 (-0.014, 0.091), 0.149		NA (NA, NA), NA	
Eye oedema, n (%)	1 (3.1)	0	0	1 (1.4)	0.920
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.200		NE (NE, NE), 0.481	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.031 (-0.092, 0.029), 0.310		0.014 (-0.013, 0.041), 0.314	

Note1: Adverse events are coded using MedDRA version 25.0.
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Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.3a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Preferred Term	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	P-Value [3]
Generalised oedema, n (%)	0	0	0	1 (1.4)	0.966
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.481	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.014 (-0.013, 0.041), 0.314	
Oedema, n (%)	0	0	0	1 (1.4)	0.966
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.481	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.014 (-0.013, 0.041), 0.314	
Eye swelling, n (%)	1 (3.1)	0	0	0	0.970
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.200		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.031 (-0.092, 0.029), 0.310		NA (NA, NA), NA	
Abdominal wall oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.3a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Preferred Term	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	P-Value [3]
Capillary leak syndrome, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Extensive interdialytic weight gain, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Gravitational oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hydraemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.3a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Preferred Term	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	P-Value [3]
Hypervolaemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Localised oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Non-pitting oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Oedema blister, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.3a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Preferred Term	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	P-Value [3]
Periorbital swelling, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Stoma site oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Swelling face, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Visceral oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=27)	United States Avapritinib 25 mg (N=44)	Germany Placebo (N=14)	Germany Avapritinib 25 mg (N=17)
Patients with at least one Grade 1 and 2 Oedema CMQ, n (%)	4 (14.8)	9 (20.5)	1 (7.1)	4 (23.5)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema peripheral, n (%)	2 (7.4)	4 (9.1)	0	1 (5.9)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Periorbital oedema, n (%)	1 (3.7)	4 (9.1)	0	1 (5.9)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Face oedema, n (%)	0	1 (2.3)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Spain		France	
	Placebo (N=3)	Avapritinib 25 mg (N=13)	Placebo (N=5)	Avapritinib 25 mg (N=10)
Patients with at least one Grade 1 and 2 Oedema CMQ, n (%)	0	7 (53.8)	0	2 (20.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema peripheral, n (%)	0	2 (15.4)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Periorbital oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Face oedema, n (%)	0	2 (15.4)	0	1 (10.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=10)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Patients with at least one Grade 1 and 2 Oedema CMQ, n (%)	0	2 (20.0)	1 (20.0)	4 (50.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema peripheral, n (%)	0	1 (10.0)	0	1 (12.5)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Periorbital oedema, n (%)	0	1 (10.0)	0	1 (12.5)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Face oedema, n (%)	0	1 (10.0)	1 (20.0)	3 (37.5)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=7)	Norway Placebo (N=2)	Norway Avapritinib 25 mg (N=5)
Patients with at least one Grade 1 and 2 Oedema CMQ, n (%)	0	1 (14.3)	0	2 (40.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema peripheral, n (%)	0	0	0	1 (20.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Periorbital oedema, n (%)	0	0	0	1 (20.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Face oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium		Italy	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=0)	Avapritinib 25 mg (N=3)
Patients with at least one Grade 1 and 2 Oedema CMQ, n (%)	0	1 (50.0)	0	1 (33.3)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema peripheral, n (%)	0	1 (50.0)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Periorbital oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Face oedema, n (%)	0	1 (50.0)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Switzerland		Sweden	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=1)	Avapritinib 25 mg (N=1)
Patients with at least one Grade 1 and 2 Oedema CMQ, n (%)	1 (100.0)	0	1 (100.0)	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema peripheral, n (%)	0	0	1 (100.0)	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Periorbital oedema, n (%)	1 (100.0)	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Face oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Patients with at least one Grade 1 and 2 Oedema CMQ, n (%)	0	1 (100.0)	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Oedema peripheral, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Periorbital oedema, n (%)	0	1 (100.0)	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Face oedema, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=27)	United States Avapritinib 25 mg (N=44)	Germany Placebo (N=14)	Germany Avapritinib 25 mg (N=17)
Eyelid oedema, n (%)	0	0	1 (7.1)	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Fluid retention, n (%)	0	1 (2.3)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Swelling of eyelid, n (%)	0	2 (4.5)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Eye oedema, n (%)	1 (3.7)	0	0	1 (5.9)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Spain		France	
	Placebo (N=3)	Avapritinib 25 mg (N=13)	Placebo (N=5)	Avapritinib 25 mg (N=10)
Eyelid oedema, n (%)	0	4 (30.8)	0	1 (10.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Fluid retention, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Swelling of eyelid, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Eye oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=10)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Eyelid oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Fluid retention, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Swelling of eyelid, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Eye oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands		Norway	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)
Eyelid oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Fluid retention, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Swelling of eyelid, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Eye oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium		Italy	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=0)	Avapritinib 25 mg (N=3)
Eyelid oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Fluid retention, n (%)	0	0	0	1 (33.3)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Swelling of eyelid, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Eye oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Switzerland		Sweden	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=1)	Avapritinib 25 mg (N=1)
Eyelid oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Fluid retention, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Swelling of eyelid, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Eye oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Eyelid oedema, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Fluid retention, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Swelling of eyelid, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Eye oedema, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=27)	United States Avapritinib 25 mg (N=44)	Germany Placebo (N=14)	Germany Avapritinib 25 mg (N=17)
Generalised oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema, n (%)	0	0	0	1 (5.9)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Eye swelling, n (%)	1 (3.7)	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Abdominal wall oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Spain		France	
	Placebo (N=3)	Avapritinib 25 mg (N=13)	Placebo (N=5)	Avapritinib 25 mg (N=10)
Generalised oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Eye swelling, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Abdominal wall oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom		Canada	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=8)
Generalised oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Eye swelling, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Abdominal wall oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands		Norway	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)
Generalised oedema, n (%)	0	1 (14.3)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Eye swelling, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Abdominal wall oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium		Italy	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=0)	Avapritinib 25 mg (N=3)
Generalised oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Eye swelling, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Abdominal wall oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Switzerland		Sweden	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=1)	Avapritinib 25 mg (N=1)
Generalised oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Eye swelling, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Abdominal wall oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Generalised oedema, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Oedema, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Eye swelling, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Abdominal wall oedema, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=27)	United States Avapritinib 25 mg (N=44)	Germany Placebo (N=14)	Germany Avapritinib 25 mg (N=17)
Capillary leak syndrome, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Extensive interdialytic weight gain, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Gravitational oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hydraemia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Spain		France	
	Placebo (N=3)	Avapritinib 25 mg (N=13)	Placebo (N=5)	Avapritinib 25 mg (N=10)
Capillary leak syndrome, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Extensive interdialytic weight gain, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Gravitational oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hydraemia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=10)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Capillary leak syndrome, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Extensive interdialytic weight gain, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Gravitational oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hydraemia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands		Norway	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)
Capillary leak syndrome, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Extensive interdialytic weight gain, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Gravitational oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hydraemia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium		Italy	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=0)	Avapritinib 25 mg (N=3)
Capillary leak syndrome, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Extensive interdialytic weight gain, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Gravitational oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hydraemia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Switzerland		Sweden	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=1)	Avapritinib 25 mg (N=1)
Capillary leak syndrome, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Extensive interdialytic weight gain, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Gravitational oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hydraemia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Capillary leak syndrome, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Extensive interdialytic weight gain, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Gravitational oedema, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Hydraemia, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=27)	United States Avapritinib 25 mg (N=44)	Germany Placebo (N=14)	Germany Avapritinib 25 mg (N=17)
Hypervolaemia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Localised oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Non-pitting oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema blister, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Spain		France	
	Placebo (N=3)	Avapritinib 25 mg (N=13)	Placebo (N=5)	Avapritinib 25 mg (N=10)
Hypervolaemia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Localised oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Non-pitting oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema blister, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom		Canada	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=8)
Hypervolaemia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Localised oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Non-pitting oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema blister, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands		Norway	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)
Hypervolaemia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Localised oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Non-pitting oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema blister, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium		Italy	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=0)	Avapritinib 25 mg (N=3)
Hypervolaemia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Localised oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Non-pitting oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema blister, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Switzerland		Sweden	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=1)	Avapritinib 25 mg (N=1)
Hypervolaemia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Localised oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Non-pitting oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema blister, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Hypervolaemia, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Localised oedema, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Non-pitting oedema, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Oedema blister, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=27)	United States Avapritinib 25 mg (N=44)	Germany Placebo (N=14)	Germany Avapritinib 25 mg (N=17)
Periorbital swelling, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Stoma site oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Swelling face, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Visceral oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Spain		France	
	Placebo (N=3)	Avapritinib 25 mg (N=13)	Placebo (N=5)	Avapritinib 25 mg (N=10)
Periorbital swelling, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Stoma site oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Swelling face, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Visceral oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom		Canada	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=8)
Periorbital swelling, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Stoma site oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Swelling face, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Visceral oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands		Norway	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)
Periorbital swelling, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Stoma site oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Swelling face, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Visceral oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium		Italy	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=0)	Avapritinib 25 mg (N=3)
Periorbital swelling, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Stoma site oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Swelling face, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Visceral oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Switzerland		Sweden	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=1)	Avapritinib 25 mg (N=1)
Periorbital swelling, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Stoma site oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Swelling face, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Visceral oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Periorbital swelling, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Stoma site oedema, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Swelling face, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Visceral oedema, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.4a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Preferred Term	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	P-Value [3]
Patients with at least one Grade 1 and 2 Oedema CMQ, n (%)	2 (9.1)	8 (21.6)	6 (13.3)	26 (30.2)	0.983
Odds Ratio (95% CIs) [1], P-Value		2.759 (0.529, 14.377), 0.215		2.817 (1.062, 7.467), 0.033	
Relative Risk (95% CIs) [2], P-Value		2.378 (0.554, 10.209), 0.244		2.267 (1.008, 5.103), 0.048	
Risk Difference (95% CIs) [2], P-Value		0.125 (-0.054, 0.304), 0.170		0.169 (0.030, 0.308), 0.017	
Oedema peripheral, n (%)	1 (4.5)	4 (10.8)	2 (4.4)	7 (8.1)	0.838
Odds Ratio (95% CIs) [1], P-Value		2.545 (0.266, 24.359), 0.403		1.905 (0.379, 9.576), 0.427	
Relative Risk (95% CIs) [2], P-Value		2.378 (0.284, 19.950), 0.425		1.831 (0.397, 8.454), 0.438	
Risk Difference (95% CIs) [2], P-Value		0.063 (-0.070, 0.195), 0.354		0.037 (-0.047, 0.120), 0.386	
Periorbital oedema, n (%)	1 (4.5)	1 (2.7)	1 (2.2)	8 (9.3)	0.255
Odds Ratio (95% CIs) [1], P-Value		0.583 (0.035, 9.822), 0.705		4.513 (0.546, 37.277), 0.128	
Relative Risk (95% CIs) [2], P-Value		0.595 (0.039, 9.036), 0.708		4.186 (0.540, 32.430), 0.170	
Risk Difference (95% CIs) [2], P-Value		-0.018 (-0.120, 0.083), 0.722		0.071 (-0.004, 0.146), 0.064	
Face oedema, n (%)	0	3 (8.1)	1 (2.2)	6 (7.0)	0.964
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.170		3.300 (0.385, 28.294), 0.251	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		3.140 (0.390, 25.283), 0.282	
Risk Difference (95% CIs) [2], P-Value		0.081 (-0.007, 0.169), 0.071		0.048 (-0.021, 0.116), 0.177	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.4a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Preferred Term	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	P-Value [3]
Eyelid oedema, n (%)	0	1 (2.7)	1 (2.2)	4 (4.7)	0.960
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.437		2.146 (0.233, 19.796), 0.491	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		2.093 (0.241, 18.175), 0.503	
Risk Difference (95% CIs) [2], P-Value		0.027 (-0.025, 0.079), 0.311		0.024 (-0.038, 0.086), 0.442	
Fluid retention, n (%)	0	0	0	2 (2.3)	0.971
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.303	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.023 (-0.009, 0.055), 0.152	
Swelling of eyelid, n (%)	0	0	0	2 (2.3)	0.971
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.303	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.023 (-0.009, 0.055), 0.152	
Eye oedema, n (%)	0	1 (2.7)	1 (2.2)	0	0.925
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.437		NE (NE, NE), 0.165	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.027 (-0.025, 0.079), 0.311		-0.022 (-0.065, 0.021), 0.312	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.4a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Preferred Term	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	P-Value [3]
Generalised oedema, n (%)	0	0	0	1 (1.2)	0.970
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.468	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.012 (-0.011, 0.034), 0.314	
Oedema, n (%)	0	0	0	1 (1.2)	0.970
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.468	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.012 (-0.011, 0.034), 0.314	
Eye swelling, n (%)	0	0	1 (2.2)	0	0.965
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.165	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.022 (-0.065, 0.021), 0.312	
Abdominal wall oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.4a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Preferred Term	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	P-Value [3]
Capillary leak syndrome, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Extensive interdialytic weight gain, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Gravitational oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hydraemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.4a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Preferred Term	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	P-Value [3]
Hypervolaemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Localised oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Non-pitting oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Oedema blister, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.4a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Preferred Term	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	P-Value [3]
Periorbital swelling, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Stoma site oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Swelling face, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Visceral oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.5a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Preferred Term	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	P-Value [3]
Patients with at least one Grade 1 and 2 Oedema CMQ, n (%)	2 (15.4)	6 (23.1)	6 (11.1)	28 (28.9)	0.508
Odds Ratio (95% CIs) [1], P-Value		1.650 (0.283, 9.603), 0.575		3.246 (1.249, 8.441), 0.012	
Relative Risk (95% CIs) [2], P-Value		1.500 (0.350, 6.428), 0.585		2.598 (1.148, 5.878), 0.022	
Risk Difference (95% CIs) [2], P-Value		0.077 (-0.177, 0.331), 0.553		0.178 (0.054, 0.301), 0.005	
Oedema peripheral, n (%)	1 (7.7)	2 (7.7)	2 (3.7)	9 (9.3)	0.516
Odds Ratio (95% CIs) [1], P-Value		1.000 (0.082, 12.164), >0.999		2.659 (0.553, 12.782), 0.206	
Relative Risk (95% CIs) [2], P-Value		1.000 (0.100, 10.037), >0.999		2.505 (0.561, 11.178), 0.229	
Risk Difference (95% CIs) [2], P-Value		0.000 (-0.177, 0.177), >0.999		0.056 (-0.021, 0.132), 0.154	
Periorbital oedema, n (%)	0	1 (3.8)	2 (3.7)	8 (8.2)	0.973
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.474		2.337 (0.478, 11.424), 0.282	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		2.227 (0.490, 10.114), 0.300	
Risk Difference (95% CIs) [2], P-Value		0.038 (-0.035, 0.112), 0.308		0.045 (-0.029, 0.120), 0.231	
Face oedema, n (%)	0	3 (11.5)	1 (1.9)	6 (6.2)	0.958
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.202		3.495 (0.410, 29.818), 0.225	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		3.340 (0.413, 27.024), 0.258	
Risk Difference (95% CIs) [2], P-Value		0.115 (-0.007, 0.238), 0.066		0.043 (-0.017, 0.103), 0.156	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.5a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Preferred Term	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	P-Value [3]
Eyelid oedema, n (%)	0	0	1 (1.9)	5 (5.2)	0.997
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		2.880 (0.328, 25.315), 0.319	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		2.784 (0.334, 23.215), 0.344	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.033 (-0.024, 0.090), 0.255	
Fluid retention, n (%)	0	1 (3.8)	0	1 (1.0)	0.996
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.474		NE (NE, NE), 0.454	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.038 (-0.035, 0.112), 0.308		0.010 (-0.010, 0.030), 0.315	
Swelling of eyelid, n (%)	0	0	0	2 (2.1)	0.976
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.288	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.021 (-0.008, 0.049), 0.153	
Eye oedema, n (%)	0	0	1 (1.9)	1 (1.0)	0.998
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.552 (0.034, 9.007), 0.672	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.557 (0.036, 8.724), 0.677	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.008 (-0.049, 0.033), 0.696	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.5a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Preferred Term	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	P-Value [3]
Generalised oedema, n (%)	0	0	0	1 (1.0)	0.975
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.454	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.010 (-0.010, 0.030), 0.315	
Oedema, n (%)	0	1 (3.8)	0	0	0.963
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.474		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.038 (-0.035, 0.112), 0.308		NA (NA, NA), NA	
Eye swelling, n (%)	1 (7.7)	0	0	0	0.971
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.152		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.077 (-0.222, 0.068), 0.298		NA (NA, NA), NA	
Abdominal wall oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.5a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Preferred Term	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	P-Value [3]
Capillary leak syndrome, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Extensive interdialytic weight gain, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Gravitational oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hydraemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.5a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Preferred Term	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	P-Value [3]
Hypervolaemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Localised oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Non-pitting oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Oedema blister, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.5a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Preferred Term	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	P-Value [3]
Periorbital swelling, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Stoma site oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Swelling face, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Visceral oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.6a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Preferred Term	Placebo (N=32)	Avapritinib 25 mg (N=63)	Placebo (N=35)	Avapritinib 25 mg (N=60)	P-Value [3]
Patients with at least one Grade 1 and 2 Oedema CMQ, n (%)	2 (6.3)	16 (25.4)	6 (17.1)	18 (30.0)	0.341
Odds Ratio (95% CIs) [1], P-Value		5.106 (1.095, 23.811), 0.024		2.071 (0.734, 5.849), 0.164	
Relative Risk (95% CIs) [2], P-Value		4.063 (0.995, 16.595), 0.051		1.750 (0.767, 3.991), 0.183	
Risk Difference (95% CIs) [2], P-Value		0.191 (0.055, 0.328), 0.006		0.129 (-0.042, 0.299), 0.139	
Oedema peripheral, n (%)	1 (3.1)	5 (7.9)	2 (5.7)	6 (10.0)	0.788
Odds Ratio (95% CIs) [1], P-Value		2.672 (0.299, 23.899), 0.362		1.833 (0.349, 9.622), 0.468	
Relative Risk (95% CIs) [2], P-Value		2.540 (0.310, 20.832), 0.385		1.750 (0.373, 8.204), 0.478	
Risk Difference (95% CIs) [2], P-Value		0.048 (-0.042, 0.138), 0.294		0.043 (-0.065, 0.151), 0.437	
Periorbital oedema, n (%)	0	2 (3.2)	2 (5.7)	7 (11.7)	0.958
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.308		2.179 (0.427, 11.128), 0.339	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		2.042 (0.449, 9.290), 0.356	
Risk Difference (95% CIs) [2], P-Value		0.032 (-0.012, 0.075), 0.151		0.060 (-0.052, 0.171), 0.297	
Face oedema, n (%)	0	4 (6.3)	1 (2.9)	5 (8.3)	0.958
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.145		3.091 (0.346, 27.596), 0.290	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		2.917 (0.355, 23.966), 0.319	
Risk Difference (95% CIs) [2], P-Value		0.063 (0.003, 0.124), 0.039		0.055 (-0.034, 0.144), 0.228	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.6a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Preferred Term	Placebo (N=32)	Avapritinib 25 mg (N=63)	Placebo (N=35)	Avapritinib 25 mg (N=60)	P-Value [3]
Eyelid oedema, n (%)	1 (3.1)	1 (1.6)	0	4 (6.7)	0.936
Odds Ratio (95% CIs) [1], P-Value		0.500 (0.030, 8.265), 0.622		NE (NE, NE), 0.119	
Relative Risk (95% CIs) [2], P-Value		0.508 (0.033, 7.858), 0.628		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.015 (-0.083, 0.052), 0.656		0.067 (0.004, 0.130), 0.038	
Fluid retention, n (%)	0	2 (3.2)	0	0	0.967
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.308		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.032 (-0.012, 0.075), 0.151		NA (NA, NA), NA	
Swelling of eyelid, n (%)	0	1 (1.6)	0	1 (1.7)	>0.999
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.474		NE (NE, NE), 0.443	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.016 (-0.015, 0.047), 0.313		0.017 (-0.016, 0.049), 0.313	
Eye oedema, n (%)	0	1 (1.6)	1 (2.9)	0	0.920
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.474		NE (NE, NE), 0.188	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.016 (-0.015, 0.047), 0.313		-0.029 (-0.084, 0.027), 0.310	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.6a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Preferred Term	Placebo (N=32)	Avapritinib 25 mg (N=63)	Placebo (N=35)	Avapritinib 25 mg (N=60)	P-Value [3]
Generalised oedema, n (%)	0	1 (1.6)	0	0	0.965
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.474		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.016 (-0.015, 0.047), 0.313		NA (NA, NA), NA	
Oedema, n (%)	0	1 (1.6)	0	0	0.965
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.474		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.016 (-0.015, 0.047), 0.313		NA (NA, NA), NA	
Eye swelling, n (%)	0	0	1 (2.9)	0	0.957
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.188	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.029 (-0.084, 0.027), 0.310	
Abdominal wall oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.6a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Preferred Term	Placebo (N=32)	Avapritinib 25 mg (N=63)	Placebo (N=35)	Avapritinib 25 mg (N=60)	P-Value [3]
Capillary leak syndrome, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Extensive interdialytic weight gain, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Gravitational oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hydraemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.6a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Preferred Term	Placebo (N=32)	Avapritinib 25 mg (N=63)	Placebo (N=35)	Avapritinib 25 mg (N=60)	P-Value [3]
Hypervolaemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Localised oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Non-pitting oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Oedema blister, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.6a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Preferred Term	Placebo (N=32)	Avapritinib 25 mg (N=63)	Placebo (N=35)	Avapritinib 25 mg (N=60)	P-Value [3]
Periorbital swelling, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Stoma site oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Swelling face, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Visceral oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.7a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Preferred Term	Placebo (N=6)	Avapritinib 25 mg (N=19)	Placebo (N=61)	Avapritinib 25 mg (N=104)	P-Value [3]
Patients with at least one Grade 1 and 2 Oedema CMQ, n (%)	0	5 (26.3)	8 (13.1)	29 (27.9)	0.963
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.160		2.562 (1.086, 6.042), 0.028	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		2.126 (1.039, 4.351), 0.039	
Risk Difference (95% CIs) [2], P-Value		0.263 (0.065, 0.461), 0.009		0.148 (0.027, 0.269), 0.017	
Oedema peripheral, n (%)	0	2 (10.5)	3 (4.9)	9 (8.7)	0.965
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.407		1.832 (0.476, 7.043), 0.372	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.760 (0.495, 6.252), 0.382	
Risk Difference (95% CIs) [2], P-Value		0.105 (-0.033, 0.243), 0.135		0.037 (-0.039, 0.114), 0.339	
Periorbital oedema, n (%)	0	1 (5.3)	2 (3.3)	8 (7.7)	0.958
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.566		2.458 (0.505, 11.972), 0.251	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		2.346 (0.515, 10.694), 0.271	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		0.044 (-0.024, 0.112), 0.203	
Face oedema, n (%)	0	2 (10.5)	1 (1.6)	7 (6.7)	0.959
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.407		4.330 (0.520, 36.068), 0.142	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		4.106 (0.517, 32.580), 0.181	
Risk Difference (95% CIs) [2], P-Value		0.105 (-0.033, 0.243), 0.135		0.051 (-0.007, 0.109), 0.084	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.7a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Preferred Term	Placebo (N=6)	Avapritinib 25 mg (N=19)	Placebo (N=61)	Avapritinib 25 mg (N=104)	P-Value [3]
Eyelid oedema, n (%)	0	0	1 (1.6)	5 (4.8)	0.994
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		3.030 (0.346, 26.563), 0.294	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		2.933 (0.351, 24.522), 0.321	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.032 (-0.020, 0.084), 0.233	
Fluid retention, n (%)	0	0	0	2 (1.9)	0.973
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.276	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.019 (-0.007, 0.046), 0.153	
Swelling of eyelid, n (%)	0	1 (5.3)	0	1 (1.0)	0.998
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.566		NE (NE, NE), 0.442	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		0.010 (-0.009, 0.028), 0.315	
Eye oedema, n (%)	0	0	1 (1.6)	1 (1.0)	0.998
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.583 (0.036, 9.484), 0.701	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.587 (0.037, 9.209), 0.704	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.007 (-0.044, 0.030), 0.719	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.7a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Preferred Term	Placebo (N=6)	Avapritinib 25 mg (N=19)	Placebo (N=61)	Avapritinib 25 mg (N=104)	P-Value [3]
Generalised oedema, n (%)	0	0	0	1 (1.0)	0.981
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.442	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.010 (-0.009, 0.028), 0.315	
Oedema, n (%)	0	1 (5.3)	0	0	0.960
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.566		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		NA (NA, NA), NA	
Eye swelling, n (%)	0	0	1 (1.6)	0	0.980
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.190	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.016 (-0.048, 0.015), 0.313	
Abdominal wall oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.7a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Preferred Term	Placebo (N=6)	Avapritinib 25 mg (N=19)	Placebo (N=61)	Avapritinib 25 mg (N=104)	P-Value [3]
Capillary leak syndrome, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Extensive interdialytic weight gain, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Gravitational oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hydraemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.7a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Preferred Term	Placebo (N=6)	Avapritinib 25 mg (N=19)	Placebo (N=61)	Avapritinib 25 mg (N=104)	P-Value [3]
Hypervolaemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Localised oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Non-pitting oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Oedema blister, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.7a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Preferred Term	Placebo (N=6)	Avapritinib 25 mg (N=19)	Placebo (N=61)	Avapritinib 25 mg (N=104)	P-Value [3]
Periorbital swelling, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Stoma site oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Swelling face, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Visceral oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.8a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Preferred Term	Placebo (N=11)	Avapritinib 25 mg (N=25)	Placebo (N=56)	Avapritinib 25 mg (N=98)	P-Value [3]
Patients with at least one Grade 1 and 2 Oedema CMQ, n (%)	2 (18.2)	6 (24.0)	6 (10.7)	28 (28.6)	0.409
Odds Ratio (95% CIs) [1], P-Value		1.421 (0.238, 8.478), 0.699		3.333 (1.285, 8.649), 0.010	
Relative Risk (95% CIs) [2], P-Value		1.320 (0.314, 5.541), 0.704		2.667 (1.176, 6.044), 0.019	
Risk Difference (95% CIs) [2], P-Value		0.058 (-0.225, 0.341), 0.687		0.179 (0.058, 0.299), 0.004	
Oedema peripheral, n (%)	0	2 (8.0)	3 (5.4)	9 (9.2)	0.954
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.334		1.787 (0.463, 6.893), 0.394	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.714 (0.484, 6.072), 0.404	
Risk Difference (95% CIs) [2], P-Value		0.080 (-0.026, 0.186), 0.140		0.038 (-0.044, 0.120), 0.361	
Periorbital oedema, n (%)	0	1 (4.0)	2 (3.6)	8 (8.2)	0.963
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.501		2.400 (0.491, 11.720), 0.266	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		2.286 (0.503, 10.391), 0.285	
Risk Difference (95% CIs) [2], P-Value		0.040 (-0.037, 0.117), 0.307		0.046 (-0.027, 0.119), 0.216	
Face oedema, n (%)	0	4 (16.0)	1 (1.8)	5 (5.1)	0.959
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.159		2.957 (0.337, 25.970), 0.306	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		2.857 (0.342, 23.846), 0.332	
Risk Difference (95% CIs) [2], P-Value		0.160 (0.016, 0.304), 0.029		0.033 (-0.023, 0.089), 0.243	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.8a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Preferred Term	Placebo (N=11)	Avapritinib 25 mg (N=25)	Placebo (N=56)	Avapritinib 25 mg (N=98)	P-Value [3]
Eyelid oedema, n (%)	0	0	1 (1.8)	5 (5.1)	0.995
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		2.957 (0.337, 25.970), 0.306	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		2.857 (0.342, 23.846), 0.332	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.033 (-0.023, 0.089), 0.243	
Fluid retention, n (%)	0	1 (4.0)	0	1 (1.0)	0.998
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.501		NE (NE, NE), 0.448	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.040 (-0.037, 0.117), 0.307		0.010 (-0.010, 0.030), 0.315	
Swelling of eyelid, n (%)	0	0	0	2 (2.0)	0.966
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.282	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.020 (-0.008, 0.048), 0.153	
Eye oedema, n (%)	1 (9.1)	0	0	1 (1.0)	0.900
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.126		NE (NE, NE), 0.448	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.091 (-0.261, 0.079), 0.294		0.010 (-0.010, 0.030), 0.315	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.8a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Preferred Term	Placebo (N=11)	Avapritinib 25 mg (N=25)	Placebo (N=56)	Avapritinib 25 mg (N=98)	P-Value [3]
Generalised oedema, n (%)	0	0	0	1 (1.0)	0.976
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.448	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.010 (-0.010, 0.030), 0.315	
Oedema, n (%)	0	0	0	1 (1.0)	0.976
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.448	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.010 (-0.010, 0.030), 0.315	
Eye swelling, n (%)	1 (9.1)	0	0	0	0.963
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.126		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.091 (-0.261, 0.079), 0.294		NA (NA, NA), NA	
Abdominal wall oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.8a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Preferred Term	Placebo (N=11)	Avapritinib 25 mg (N=25)	Placebo (N=56)	Avapritinib 25 mg (N=98)	P-Value [3]
Capillary leak syndrome, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Extensive interdialytic weight gain, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Gravitational oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hydraemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.8a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Preferred Term	Placebo (N=11)	Avapritinib 25 mg (N=25)	Placebo (N=56)	Avapritinib 25 mg (N=98)	P-Value [3]
Hypervolaemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Localised oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Non-pitting oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Oedema blister, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.1.2.8a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
Preferred Term	Placebo (N=11)	Avapritinib 25 mg (N=25)	Placebo (N=56)	Avapritinib 25 mg (N=98)	P-Value [3]
Periorbital swelling, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Stoma site oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Swelling face, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Visceral oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.2.2.1a
Summary of Grade 3 and Higher Oedema CMQ by Preferred Term by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.2.2.2a
Summary of Grade 3 and Higher Oedema CMQ by Preferred Term by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.2.2.3a
Summary of Grade 3 and Higher Oedema CMQ by Preferred Term by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.2.2.9a
Summary of Grade 3 and Higher Oedema CMQ by Preferred Term by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.2.2.4a
Summary of Grade 3 and Higher Oedema CMQ by Preferred Term by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.2.2.5a
Summary of Grade 3 and Higher Oedema CMQ by Preferred Term by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.2.2.6a
Summary of Grade 3 and Higher Oedema CMQ by Preferred Term by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.2.2.7a
Summary of Grade 3 and Higher Oedema CMQ by Preferred Term by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.2.2.2.8a
Summary of Grade 3 and Higher Oedema CMQ by Preferred Term by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
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Table 35.3.1.16.6.2.1a
Time to Onset of Oedema CMQ by Age Group
Per Protocol Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
	Placebo (N=56)	Avapritinib 25 mg (N=117)	Placebo (N=11)	Avapritinib 25 mg (N=6)	P-Value [2]
Patients with Events (n (%))	8 (14.3)	29 (24.8)	0	5 (83.3)	NA
Patients Censored (n (%))	48 (85.7)	88 (75.2)	11 (100)	1 (16.7)	
Kaplan-Meier Estimates (Months)					
Median (95% CI)	6.34 (-, -)	- (-, -)	- (-, -)	1.23 (0.49, 5.22)	
25th, 75th percentiles	6.34, 6.34	5.52, -	-, -	0.49, 5.22	
Min, Max	0.10, 6.34	0.03, 6.51*	1.87*, 5.59*	0.26, 5.55*	
3 Months (95% CI)	8.9 (1.5, 16.4)	19.9 (12.6, 27.2)	0.0 (0.0, 0.0)	66.7 (28.9, 100)	
6 Months (95% CI)	13.0 (4.0, 22.0)	25.5 (17.4, 33.5)	- (-, -)	- (-, -)	
9 Months (95% CI)	100 (100, 100)	- (-, -)	- (-, -)	- (-, -)	
12 Months (95% CI)	100 (100, 100)	- (-, -)	- (-, -)	- (-, -)	
Hazard Ratio (95% CI) [1]		1.846 (0.844, 4.038)		- (-, -)	
p-value		0.1250		NA	

Abbreviations: CMQ = Customized MedDRA Queries.
Note: * = censored observation.
Notes: Time to first onset of Oedema CMQ is defined as from day 1 of avapritinib/placebo to the first Oedema CMQ start date. For patients without Oedema CMQ, time to first onset will be censored at the minimum of date of last study drug dose + 30 days, cutoff date, death date, or end of study date.
[1] Hazard Ratio is calculated based on Cox proportional hazards model. HR < 1 suggests that Avapritinib experiences a lower event probability during a unit of time than placebo.
[2] Two-sided p-values for treatment-by-subgroup interaction are from Cox proportional hazards model with treatment, subgroup, treatment*subgroup in the model.
Cross References: Listing 16.2.6.1
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Table 35.3.1.16.6.2.2a
Time to Onset of Oedema CMQ by Sex
Per Protocol Population, Part 2 (Part 2 Baseline)

	Male		Female		
	Placebo (N=15)	Avapritinib 25 mg (N=35)	Placebo (N=52)	Avapritinib 25 mg (N=88)	P-Value [2]
Patients with Events (n (%))	1 (6.7)	7 (20.0)	7 (13.5)	27 (30.7)	0.824
Patients Censored (n (%))	14 (93.3)	28 (80.0)	45 (86.5)	61 (69.3)	
Kaplan-Meier Estimates (Months)					
Median (95% CI)	- (-, -)	- (-, -)	6.34 (-, -)	- (-, -)	
25th, 75th percentiles	-, -	-, -	6.34, 6.34	3.52, -	
Min, Max	1.77, 6.21*	0.49, 6.05*	0.10, 6.34	0.03, 6.51*	
3 Months (95% CI)	6.7 (0.0, 19.3)	20.0 (6.7, 33.3)	7.7 (0.4, 14.9)	23.1 (14.2, 32.0)	
6 Months (95% CI)	6.7 (0.0, 19.3)	20.0 (6.7, 33.3)	12.2 (3.0, 21.4)	31.8 (21.8, 41.8)	
9 Months (95% CI)	- (-, -)	- (-, -)	100 (100, 100)	- (-, -)	
12 Months (95% CI)	- (-, -)	- (-, -)	100 (100, 100)	- (-, -)	
Hazard Ratio (95% CI) [1]		3.203 (0.394, 26.029)		2.501 (1.089, 5.748)	
p-value		0.2762		0.0308	

Abbreviations: CMQ = Customized MedDRA Queries.
Note: * = censored observation.
Notes: Time to first onset of Oedema CMQ is defined as from day 1 of avapritinib/placebo to the first Oedema CMQ start date. For patients without Oedema CMQ, time to first onset will be censored at the minimum of date of last study drug dose + 30 days, cutoff date, death date, or end of study date.
[1] Hazard Ratio is calculated based on Cox proportional hazards model. HR < 1 suggests that Avapritinib experiences a lower event probability during a unit of time than placebo.
[2] Two-sided p-values for treatment-by-subgroup interaction are from Cox proportional hazards model with treatment, subgroup, treatment*subgroup in the model.
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-tte-pp-subgrp-a.sas Date: 8:05/16NOV2023

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Table 35.3.1.16.6.2.3a
Time to Onset of Oedema CMQ by Region
Per Protocol Population, Part 2 (Part 2 Baseline)

	North America		Europe		
	Placebo (N=32)	Avapritinib 25 mg (N=52)	Placebo (N=35)	Avapritinib 25 mg (N=71)	P-Value [2]
Patients with Events (n (%))	5 (15.6)	13 (25.0)	3 (8.6)	21 (29.6)	0.366
Patients Censored (n (%))	27 (84.4)	39 (75.0)	32 (91.4)	50 (70.4)	
Kaplan-Meier Estimates (Months)					
Median (95% CI)	6.34 (-, -)	- (-, -)	- (-, -)	- (-, -)	
25th, 75th percentiles	6.34, 6.34	4.86, -	-, -	2.99, -	
Min, Max	0.85, 6.34	0.03, 6.31*	0.10, 6.28*	0.26, 6.51*	
3 Months (95% CI)	6.3 (0.0, 14.6)	17.4 (7.0, 27.7)	8.6 (0.0, 17.8)	25.8 (15.5, 36.1)	
6 Months (95% CI)	13.6 (1.1, 26.1)	25.2 (13.4, 37.1)	8.6 (0.0, 17.8)	30.6 (19.6, 41.6)	
9 Months (95% CI)	100 (100, 100)	- (-, -)	- (-, -)	- (-, -)	
12 Months (95% CI)	100 (100, 100)	- (-, -)	- (-, -)	- (-, -)	
Hazard Ratio (95% CI) [1]		2.114 (0.689, 6.486)		3.772 (1.125, 12.649)	
p-value		0.1904		0.0315	

Abbreviations: CMQ = Customized MedDRA Queries.
Note: * = censored observation.
Notes: Time to first onset of Oedema CMQ is defined as from day 1 of avapritinib/placebo to the first Oedema CMQ start date. For patients without Oedema CMQ, time to first onset will be censored at the minimum of date of last study drug dose + 30 days, cutoff date, death date, or end of study date.
[1] Hazard Ratio is calculated based on Cox proportional hazards model. HR < 1 suggests that Avapritinib experiences a lower event probability during a unit of time than placebo.
[2] Two-sided p-values for treatment-by-subgroup interaction are from Cox proportional hazards model with treatment, subgroup, treatment*subgroup in the model.
Cross References: Listing 16.2.6.1
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Table 35.3.1.16.6.2.9a
Time to Onset of Oedema CMQ by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

	United States		Germany	
	Placebo (N=27)	Avapritinib 25 mg (N=44)	Placebo (N=14)	Avapritinib 25 mg (N=17)
Patients with Events (n (%))	4 (14.8)	9 (20.5)	1 (7.1)	4 (23.5)
Patients Censored (n (%))	23 (85.2)	35 (79.5)	13 (92.9)	13 (76.5)
Kaplan-Meier Estimates (Months)				
Median (95% CI)	6.34 (-, -)	- (-, -)	- (-, -)	- (5.52, -)
25th, 75th percentiles	6.34, 6.34	-, -	-, -	5.52, -
Min, Max	0.85, 6.34	0.03, 6.11*	0.26, 5.88*	0.43, 6.05*
3 Months (95% CI)	7.4 (0.0, 17.3)	13.7 (3.5, 23.9)	7.1 (0.0, 20.6)	17.6 (0.0, 35.8)
6 Months (95% CI)	12.3 (0.0, 25.5)	20.7 (8.6, 32.7)	- (-, -)	26.8 (3.4, 50.2)
9 Months (95% CI)	100 (100, 100)	- (-, -)	- (-, -)	- (-, -)
12 Months (95% CI)	100 (100, 100)	- (-, -)	- (-, -)	- (-, -)
Hazard Ratio (95% CI) [1]		1.897 (0.513, 7.008)		3.568 (0.397, 32.100)
p-value		0.3370		0.2564

Abbreviations: CMQ = Customized MedDRA Queries.
Note: * = censored observation.
Notes: Time to first onset of Oedema CMQ is defined as from day 1 of avapritinib/placebo to the first Oedema CMQ start date. For patients without Oedema CMQ, time to first onset will be censored at the minimum of date of last study drug dose + 30 days, cutoff date, death date, or end of study date.
[1] Hazard Ratio is calculated based on Cox proportional hazards model. HR < 1 suggests that Avapritinib experiences a lower event probability during a unit of time than placebo.
[2] Two-sided p-values for treatment-by-subgroup interaction are from Cox proportional hazards model with treatment, subgroup, treatment*subgroup in the model.
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-tte-pp-subgrp-a.sas Date: 8:05/16NOV2023

Table 35.3.1.16.6.2.9a
Time to Onset of Oedema CMQ by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

	Spain		France	
	Placebo (N=3)	Avapritinib 25 mg (N=13)	Placebo (N=5)	Avapritinib 25 mg (N=10)
Patients with Events (n (%))	0	7 (53.8)	0	2 (20.0)
Patients Censored (n (%))	3 (100)	6 (46.2)	5 (100)	8 (80.0)
Kaplan-Meier Estimates (Months)				
Median (95% CI)	- (-, -)	3.65 (1.97, -)	- (-, -)	- (-, -)
25th, 75th percentiles	-, -	1.97, -	-, -	-, -
Min, Max	5.55*, 6.24*	0.26, 6.41*	5.45*, 5.55*	1.51, 5.72*
3 Months (95% CI)	0.0 (0.0, 0.0)	46.2 (19.1, 73.3)	0.0 (0.0, 0.0)	10.0 (0.0, 28.6)
6 Months (95% CI)	0.0 (0.0, 0.0)	53.8 (26.7, 80.9)	- (-, -)	- (-, -)
9 Months (95% CI)	- (-, -)	- (-, -)	- (-, -)	- (-, -)
12 Months (95% CI)	- (-, -)	- (-, -)	- (-, -)	- (-, -)
Hazard Ratio (95% CI) [1]		- (-, -)		- (-, -)
p-value		NA		NA

Abbreviations: CMQ = Customized MedDRA Queries.
Note: * = censored observation.
Notes: Time to first onset of Oedema CMQ is defined as from day 1 of avapritinib/placebo to the first Oedema CMQ start date. For patients without Oedema CMQ, time to first onset will be censored at the minimum of date of last study drug dose + 30 days, cutoff date, death date, or end of study date.
[1] Hazard Ratio is calculated based on Cox proportional hazards model. HR < 1 suggests that Avapritinib experiences a lower event probability during a unit of time than placebo.
[2] Two-sided p-values for treatment-by-subgroup interaction are from Cox proportional hazards model with treatment, subgroup, treatment*subgroup in the model.
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-tte-pp-subgrp-a.sas Date: 8:05/16NOV2023

Table 35.3.1.16.6.2.9a
Time to Onset of Oedema CMQ by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

	United Kingdom		Canada	
	Placebo (N=5)	Avapritinib 25 mg (N=10)	Placebo (N=5)	Avapritinib 25 mg (N=8)
Patients with Events (n (%))	0	2 (20.0)	1 (20.0)	4 (50.0)
Patients Censored (n (%))	5 (100)	8 (80.0)	4 (80.0)	4 (50.0)
Kaplan-Meier Estimates (Months)				
Median (95% CI)	- (-, -)	- (-, -)	- (3.42, -)	- (1.28, -)
25th, 75th percentiles	-, -	-, -	-, -	1.43, -
Min, Max	5.55*, 6.28*	0.49, 6.51*	3.42, 5.59*	0.92, 6.31*
3 Months (95% CI)	0.0 (0.0, 0.0)	20.0 (0.0, 44.8)	0.0 (0.0, 0.0)	37.5 (4.0, 71.0)
6 Months (95% CI)	0.0 (0.0, 0.0)	20.0 (0.0, 44.8)	- (-, -)	50.0 (15.4, 84.6)
9 Months (95% CI)	- (-, -)	- (-, -)	- (-, -)	- (-, -)
12 Months (95% CI)	- (-, -)	- (-, -)	- (-, -)	- (-, -)
Hazard Ratio (95% CI) [1]		- (-, -)		2.995 (0.333, 26.974)
p-value		NA		0.3279

Abbreviations: CMQ = Customized MedDRA Queries.
Note: * = censored observation.
Notes: Time to first onset of Oedema CMQ is defined as from day 1 of avapritinib/placebo to the first Oedema CMQ start date. For patients without Oedema CMQ, time to first onset will be censored at the minimum of date of last study drug dose + 30 days, cutoff date, death date, or end of study date.
[1] Hazard Ratio is calculated based on Cox proportional hazards model. HR < 1 suggests that Avapritinib experiences a lower event probability during a unit of time than placebo.
[2] Two-sided p-values for treatment-by-subgroup interaction are from Cox proportional hazards model with treatment, subgroup, treatment*subgroup in the model.
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-tte-pp-subgrp-a.sas Date: 8:05/16NOV2023

Table 35.3.1.16.6.2.9a
Time to Onset of Oedema CMQ by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

	Netherlands		Norway	
	Placebo (N=3)	Avapritinib 25 mg (N=7)	Placebo (N=2)	Avapritinib 25 mg (N=5)
Patients with Events (n (%))	0	1 (14.3)	0	2 (40.0)
Patients Censored (n (%))	3 (100)	6 (85.7)	2 (100)	3 (60.0)
Kaplan-Meier Estimates (Months)				
Median (95% CI)	- (-, -)	- (-, -)	- (-, -)	- (2.79, -)
25th, 75th percentiles	-, -	-, -	-, -	2.99, -
Min, Max	5.52*, 5.55*	0.95*, 5.59*	5.45*, 5.45*	2.79, 5.55*
3 Months (95% CI)	0.0 (0.0, 0.0)	16.7 (0.0, 46.5)	0.0 (0.0, 0.0)	40.0 (0.0, 82.9)
6 Months (95% CI)	- (-, -)	- (-, -)	- (-, -)	- (-, -)
9 Months (95% CI)	- (-, -)	- (-, -)	- (-, -)	- (-, -)
12 Months (95% CI)	- (-, -)	- (-, -)	- (-, -)	- (-, -)
Hazard Ratio (95% CI) [1]		- (-, -)		- (-, -)
p-value		NA		NA

Abbreviations: CMQ = Customized MedDRA Queries.
Note: * = censored observation.
Notes: Time to first onset of Oedema CMQ is defined as from day 1 of avapritinib/placebo to the first Oedema CMQ start date. For patients without Oedema CMQ, time to first onset will be censored at the minimum of date of last study drug dose + 30 days, cutoff date, death date, or end of study date.
[1] Hazard Ratio is calculated based on Cox proportional hazards model. HR < 1 suggests that Avapritinib experiences a lower event probability during a unit of time than placebo.
[2] Two-sided p-values for treatment-by-subgroup interaction are from Cox proportional hazards model with treatment, subgroup, treatment*subgroup in the model.
Cross References: Listing 16.2.6.1
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Table 35.3.1.16.6.2.9a
Time to Onset of Oedema CMQ by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

	Belgium		Italy	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=0)	Avapritinib 25 mg (N=3)
Patients with Events (n (%))	0	1 (50.0)	0	1 (33.3)
Patients Censored (n (%))	1 (100)	1 (50.0)	0	2 (66.7)
Kaplan-Meier Estimates (Months)				
Median (95% CI)	- (-, -)	- (2.43, -)	- (-, -)	- (2.46, -)
25th, 75th percentiles	-, -	2.43, -	-, -	2.46, -
Min, Max	5.45*, 5.45*	2.43, 5.55*	-, -	2.46, 5.55*
3 Months (95% CI)	0.0 (0.0, 0.0)	50.0 (0.0, 100)	- (-, -)	33.3 (0.0, 86.7)
6 Months (95% CI)	- (-, -)	- (-, -)	- (-, -)	- (-, -)
9 Months (95% CI)	- (-, -)	- (-, -)	- (-, -)	- (-, -)
12 Months (95% CI)	- (-, -)	- (-, -)	- (-, -)	- (-, -)
Hazard Ratio (95% CI) [1]		- (-, -)		- (-, -)
p-value		NA		NA

Abbreviations: CMQ = Customized MedDRA Queries.
Note: * = censored observation.
Notes: Time to first onset of Oedema CMQ is defined as from day 1 of avapritinib/placebo to the first Oedema CMQ start date. For patients without Oedema CMQ, time to first onset will be censored at the minimum of date of last study drug dose + 30 days, cutoff date, death date, or end of study date.
[1] Hazard Ratio is calculated based on Cox proportional hazards model. HR < 1 suggests that Avapritinib experiences a lower event probability during a unit of time than placebo.
[2] Two-sided p-values for treatment-by-subgroup interaction are from Cox proportional hazards model with treatment, subgroup, treatment*subgroup in the model.
Cross References: Listing 16.2.6.1
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Table 35.3.1.16.6.2.9a
Time to Onset of Oedema CMQ by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

	Switzerland		Sweden	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=1)	Avapritinib 25 mg (N=1)
Patients with Events (n (%))	1 (100)	0	1 (100)	0
Patients Censored (n (%))	0	2 (100)	0	1 (100)
Kaplan-Meier Estimates (Months)				
Median (95% CI)	0.10 (-, -)	- (-, -)	1.77 (-, -)	- (-, -)
25th, 75th percentiles	0.10, 0.10	-, -	1.77, 1.77	-, -
Min, Max	0.10, 0.10	5.49*, 5.72*	1.77, 1.77	5.55*, 5.55*
3 Months (95% CI)	100 (100, 100)	0.0 (0.0, 0.0)	100 (100, 100)	0.0 (0.0, 0.0)
6 Months (95% CI)	100 (100, 100)	- (-, -)	100 (100, 100)	- (-, -)
9 Months (95% CI)	100 (100, 100)	- (-, -)	100 (100, 100)	- (-, -)
12 Months (95% CI)	100 (100, 100)	- (-, -)	100 (100, 100)	- (-, -)
Hazard Ratio (95% CI) [1]		- (-, -)	- (-, -)	
p-value		NA	NA	

Abbreviations: CMQ = Customized MedDRA Queries.
Note: * = censored observation.
Notes: Time to first onset of Oedema CMQ is defined as from day 1 of avapritinib/placebo to the first Oedema CMQ start date. For patients without Oedema CMQ, time to first onset will be censored at the minimum of date of last study drug dose + 30 days, cutoff date, death date, or end of study date.
[1] Hazard Ratio is calculated based on Cox proportional hazards model. HR < 1 suggests that Avapritinib experiences a lower event probability during a unit of time than placebo.
[2] Two-sided p-values for treatment-by-subgroup interaction are from Cox proportional hazards model with treatment, subgroup, treatment*subgroup in the model.
Cross References: Listing 16.2.6.1
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Table 35.3.1.16.6.2.9a
Time to Onset of Oedema CMQ by Country
Per Protocol Population, Part 2 (Part 2 Baseline)

	Denmark		
	Placebo (N=0)	Avapritinib 25 mg (N=1)	P-Value [2]
Patients with Events (n (%))	0	1 (100)	NA
Patients Censored (n (%))	0	0	
Kaplan-Meier Estimates (Months)			
Median (95% CI)	- (-, -)	0.36 (-, -)	
25th, 75th percentiles	-, -	0.36, 0.36	
Min, Max	-, -	0.36, 0.36	
3 Months (95% CI)	- (-, -)	100 (100, 100)	
6 Months (95% CI)	- (-, -)	100 (100, 100)	
9 Months (95% CI)	- (-, -)	100 (100, 100)	
12 Months (95% CI)	- (-, -)	100 (100, 100)	
Hazard Ratio (95% CI) [1]		- (-, -)	
p-value		NA	

Abbreviations: CMQ = Customized MedDRA Queries.
Note: * = censored observation.
Notes: Time to first onset of Oedema CMQ is defined as from day 1 of avapritinib/placebo to the first Oedema CMQ start date. For patients without Oedema CMQ, time to first onset will be censored at the minimum of date of last study drug dose + 30 days, cutoff date, death date, or end of study date.
[1] Hazard Ratio is calculated based on Cox proportional hazards model. HR < 1 suggests that Avapritinib experiences a lower event probability during a unit of time than placebo.
[2] Two-sided p-values for treatment-by-subgroup interaction are from Cox proportional hazards model with treatment, subgroup, treatment*subgroup in the model.
Cross References: Listing 16.2.6.1
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Table 35.3.1.16.6.2.4a
Time to Onset of Oedema CMQ by Baseline ISM Status
Per Protocol Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
	Placebo (N=22)	Avapritinib 25 mg (N=37)	Placebo (N=45)	Avapritinib 25 mg (N=86)	P-Value [2]
Patients with Events (n (%))	2 (9.1)	8 (21.6)	6 (13.3)	26 (30.2)	0.926
Patients Censored (n (%))	20 (90.9)	29 (78.4)	39 (86.7)	60 (69.8)	
Kaplan-Meier Estimates (Months)					
Median (95% CI)	- (-, -)	- (-, -)	6.34 (-, -)	- (-, -)	
25th, 75th percentiles	-, -	-, -	6.34, 6.34	3.52, -	
Min, Max	0.10, 6.08*	0.43, 6.41*	0.26, 6.34	0.03, 6.51*	
3 Months (95% CI)	4.5 (0.0, 13.2)	18.9 (6.3, 31.5)	8.9 (0.6, 17.2)	23.6 (14.6, 32.7)	
6 Months (95% CI)	10.5 (0.0, 24.5)	21.6 (8.4, 34.9)	11.2 (1.9, 20.4)	31.3 (21.2, 41.3)	
9 Months (95% CI)	- (-, -)	- (-, -)	100 (100, 100)	- (-, -)	
12 Months (95% CI)	- (-, -)	- (-, -)	100 (100, 100)	- (-, -)	
Hazard Ratio (95% CI) [1]		2.476 (0.525, 11.662)		2.575 (1.059, 6.263)	
p-value		0.2517		0.0370	

Abbreviations: CMQ = Customized MedDRA Queries.
Note: * = censored observation.
Notes: Time to first onset of Oedema CMQ is defined as from day 1 of avapritinib/placebo to the first Oedema CMQ start date. For patients without Oedema CMQ, time to first onset will be censored at the minimum of date of last study drug dose + 30 days, cutoff date, death date, or end of study date.
[1] Hazard Ratio is calculated based on Cox proportional hazards model. HR < 1 suggests that Avapritinib experiences a lower event probability during a unit of time than placebo.
[2] Two-sided p-values for treatment-by-subgroup interaction are from Cox proportional hazards model with treatment, subgroup, treatment*subgroup in the model.
Cross References: Listing 16.2.6.1
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Table 35.3.1.16.6.2.5a
Time to Onset of Oedema CMQ by Baseline Serum Tryptase Level
Per Protocol Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
	Placebo (N=13)	Avapritinib 25 mg (N=26)	Placebo (N=54)	Avapritinib 25 mg (N=97)	P-Value [2]
Patients with Events (n (%))	2 (15.4)	6 (23.1)	6 (11.1)	28 (28.9)	0.568
Patients Censored (n (%))	11 (84.6)	20 (76.9)	48 (88.9)	69 (71.1)	
Kaplan-Meier Estimates (Months)					
Median (95% CI)	6.34 (-, -)	- (-, -)	- (-, -)	- (-, -)	
25th, 75th percentiles	6.34, 6.34	-, -	-, -	3.35, -	
Min, Max	1.77, 6.34	1.58, 6.11*	0.10, 6.28*	0.03, 6.51*	
3 Months (95% CI)	7.7 (0.0, 22.2)	15.4 (1.5, 29.3)	7.4 (0.4, 14.4)	24.1 (15.5, 32.6)	
6 Months (95% CI)	7.7 (0.0, 22.2)	24.0 (7.1, 40.9)	11.7 (2.8, 20.7)	29.5 (20.3, 38.6)	
9 Months (95% CI)	100 (100, 100)	- (-, -)	- (-, -)	- (-, -)	
12 Months (95% CI)	100 (100, 100)	- (-, -)	- (-, -)	- (-, -)	
Hazard Ratio (95% CI) [1]		2.983 (0.359, 24.803)		2.875 (1.190, 6.947)	
p-value		0.3118		0.0190	

Abbreviations: CMQ = Customized MedDRA Queries.
Note: * = censored observation.
Notes: Time to first onset of Oedema CMQ is defined as from day 1 of avapritinib/placebo to the first Oedema CMQ start date. For patients without Oedema CMQ, time to first onset will be censored at the minimum of date of last study drug dose + 30 days, cutoff date, death date, or end of study date.
[1] Hazard Ratio is calculated based on Cox proportional hazards model. HR < 1 suggests that Avapritinib experiences a lower event probability during a unit of time than placebo.
[2] Two-sided p-values for treatment-by-subgroup interaction are from Cox proportional hazards model with treatment, subgroup, treatment*subgroup in the model.
Cross References: Listing 16.2.6.1
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CSR Germany

Table 35.3.1.16.6.2.6a
Time to Onset of Oedema CMQ by Baseline Best Supportive Care (BSC)
Per Protocol Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
	Placebo (N=32)	Avapritinib 25 mg (N=63)	Placebo (N=35)	Avapritinib 25 mg (N=60)	P-Value [2]
Patients with Events (n (%))	2 (6.3)	16 (25.4)	6 (17.1)	18 (30.0)	0.397
Patients Censored (n (%))	30 (93.8)	47 (74.6)	29 (82.9)	42 (70.0)	
Kaplan-Meier Estimates (Months)					
Median (95% CI)	- (-, -)	- (-, -)	6.34 (-, -)	- (-, -)	
25th, 75th percentiles	-, -	5.52, -	6.34, 6.34	2.99, -	
Min, Max	0.26, 5.88*	0.43, 6.41*	0.10, 6.34	0.03, 6.51*	
3 Months (95% CI)	6.3 (0.0, 14.6)	19.2 (9.5, 29.0)	8.6 (0.0, 17.8)	25.4 (14.3, 36.5)	
6 Months (95% CI)	- (-, -)	26.1 (15.1, 37.2)	15.1 (2.8, 27.5)	30.6 (18.8, 42.4)	
9 Months (95% CI)	- (-, -)	- (-, -)	100 (100, 100)	- (-, -)	
12 Months (95% CI)	- (-, -)	- (-, -)	100 (100, 100)	- (-, -)	
Hazard Ratio (95% CI) [1]		4.287 (0.986, 18.651)		1.985 (0.787, 5.007)	
p-value		0.0523		0.1465	

Abbreviations: CMQ = Customized MedDRA Queries.
Note: * = censored observation.
Notes: Time to first onset of Oedema CMQ is defined as from day 1 of avapritinib/placebo to the first Oedema CMQ start date. For patients without Oedema CMQ, time to first onset will be censored at the minimum of date of last study drug dose + 30 days, cutoff date, death date, or end of study date.
[1] Hazard Ratio is calculated based on Cox proportional hazards model. HR < 1 suggests that Avapritinib experiences a lower event probability during a unit of time than placebo.
[2] Two-sided p-values for treatment-by-subgroup interaction are from Cox proportional hazards model with treatment, subgroup, treatment*subgroup in the model.
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-tte-pp-subgrp-a.sas Date: 8:05/16NOV2023

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Table 35.3.1.16.6.2.7a
Time to Onset of Oedema CMQ by Prior Cytoreductive Therapy
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
	Placebo (N=6)	Avapritinib 25 mg (N=19)	Placebo (N=61)	Avapritinib 25 mg (N=104)	P-Value [2]
Patients with Events (n (%))	0	5 (26.3)	8 (13.1)	29 (27.9)	NA
Patients Censored (n (%))	6 (100)	14 (73.7)	53 (86.9)	75 (72.1)	
Kaplan-Meier Estimates (Months)					
Median (95% CI)	- (-, -)	- (-, -)	6.34 (-, -)	- (-, -)	
25th, 75th percentiles	-, -	5.52, -	6.34, 6.34	3.52, -	
Min, Max	3.88*, 6.21*	0.92, 6.11*	0.10, 6.34	0.03, 6.51*	
3 Months (95% CI)	0.0 (0.0, 0.0)	15.8 (0.0, 32.2)	8.2 (1.3, 15.1)	23.4 (15.2, 31.5)	
6 Months (95% CI)	0.0 (0.0, 0.0)	28.0 (6.9, 49.0)	12.0 (3.6, 20.4)	28.3 (19.6, 37.0)	
9 Months (95% CI)	- (-, -)	- (-, -)	100 (100, 100)	- (-, -)	
12 Months (95% CI)	- (-, -)	- (-, -)	100 (100, 100)	- (-, -)	
Hazard Ratio (95% CI) [1]		- (-, -)		2.294 (1.048, 5.020)	
p-value		NA		0.0377	

Abbreviations: CMQ = Customized MedDRA Queries.
Note: * = censored observation.
Notes: Time to first onset of Oedema CMQ is defined as from day 1 of avapritinib/placebo to the first Oedema CMQ start date. For patients without Oedema CMQ, time to first onset will be censored at the minimum of date of last study drug dose + 30 days, cutoff date, death date, or end of study date.
[1] Hazard Ratio is calculated based on Cox proportional hazards model. HR < 1 suggests that Avapritinib experiences a lower event probability during a unit of time than placebo.
[2] Two-sided p-values for treatment-by-subgroup interaction are from Cox proportional hazards model with treatment, subgroup, treatment*subgroup in the model.
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-tte-pp-subgrp-a.sas Date: 8:05/16NOV2023

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Table 35.3.1.16.6.2.8a
Time to Onset of Oedema CMQ by Baseline Opioid Use
Per Protocol Population, Part 2 (Part 2 Baseline)

	Yes		No		
	Placebo (N=11)	Avapritinib 25 mg (N=25)	Placebo (N=56)	Avapritinib 25 mg (N=98)	P-Value [2]
Patients with Events (n (%))	2 (18.2)	6 (24.0)	6 (10.7)	28 (28.6)	0.551
Patients Censored (n (%))	9 (81.8)	19 (76.0)	50 (89.3)	70 (71.4)	
Kaplan-Meier Estimates (Months)					
Median (95% CI)	6.34 (-, -)	- (-, -)	- (-, -)	- (-, -)	
25th, 75th percentiles	6.34, 6.34	2.46, -	-, -	4.80, -	
Min, Max	0.85, 6.34	0.26, 6.51*	0.10, 6.28*	0.03, 6.41*	
3 Months (95% CI)	9.1 (0.0, 26.1)	25.2 (7.7, 42.7)	7.1 (0.4, 13.9)	21.6 (13.4, 29.7)	
6 Months (95% CI)	9.1 (0.0, 26.1)	25.2 (7.7, 42.7)	11.3 (2.7, 19.9)	29.0 (19.9, 38.1)	
9 Months (95% CI)	100 (100, 100)	- (-, -)	- (-, -)	- (-, -)	
12 Months (95% CI)	100 (100, 100)	- (-, -)	- (-, -)	- (-, -)	
Hazard Ratio (95% CI) [1]		1.584 (0.316, 7.946)		2.874 (1.190, 6.942)	
p-value		0.5763		0.0190	

Abbreviations: CMQ = Customized MedDRA Queries.
Note: * = censored observation.
Notes: Time to first onset of Oedema CMQ is defined as from day 1 of avapritinib/placebo to the first Oedema CMQ start date. For patients without Oedema CMQ, time to first onset will be censored at the minimum of date of last study drug dose + 30 days, cutoff date, death date, or end of study date.
[1] Hazard Ratio is calculated based on Cox proportional hazards model. HR < 1 suggests that Avapritinib experiences a lower event probability during a unit of time than placebo.
[2] Two-sided p-values for treatment-by-subgroup interaction are from Cox proportional hazards model with treatment, subgroup, treatment*subgroup in the model.
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-tte-pp-subgrp-a.sas Date: 8:05/16NOV2023

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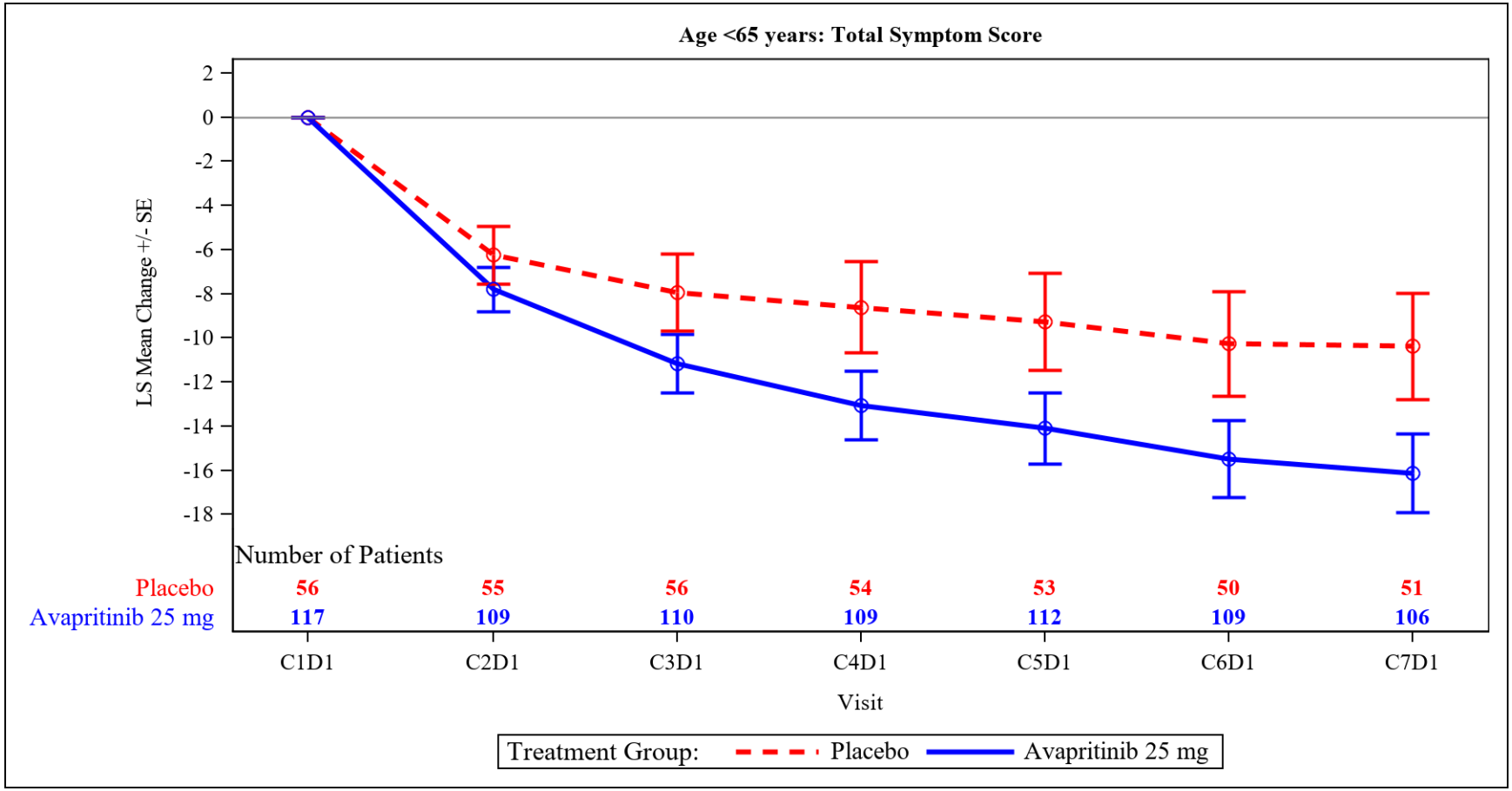
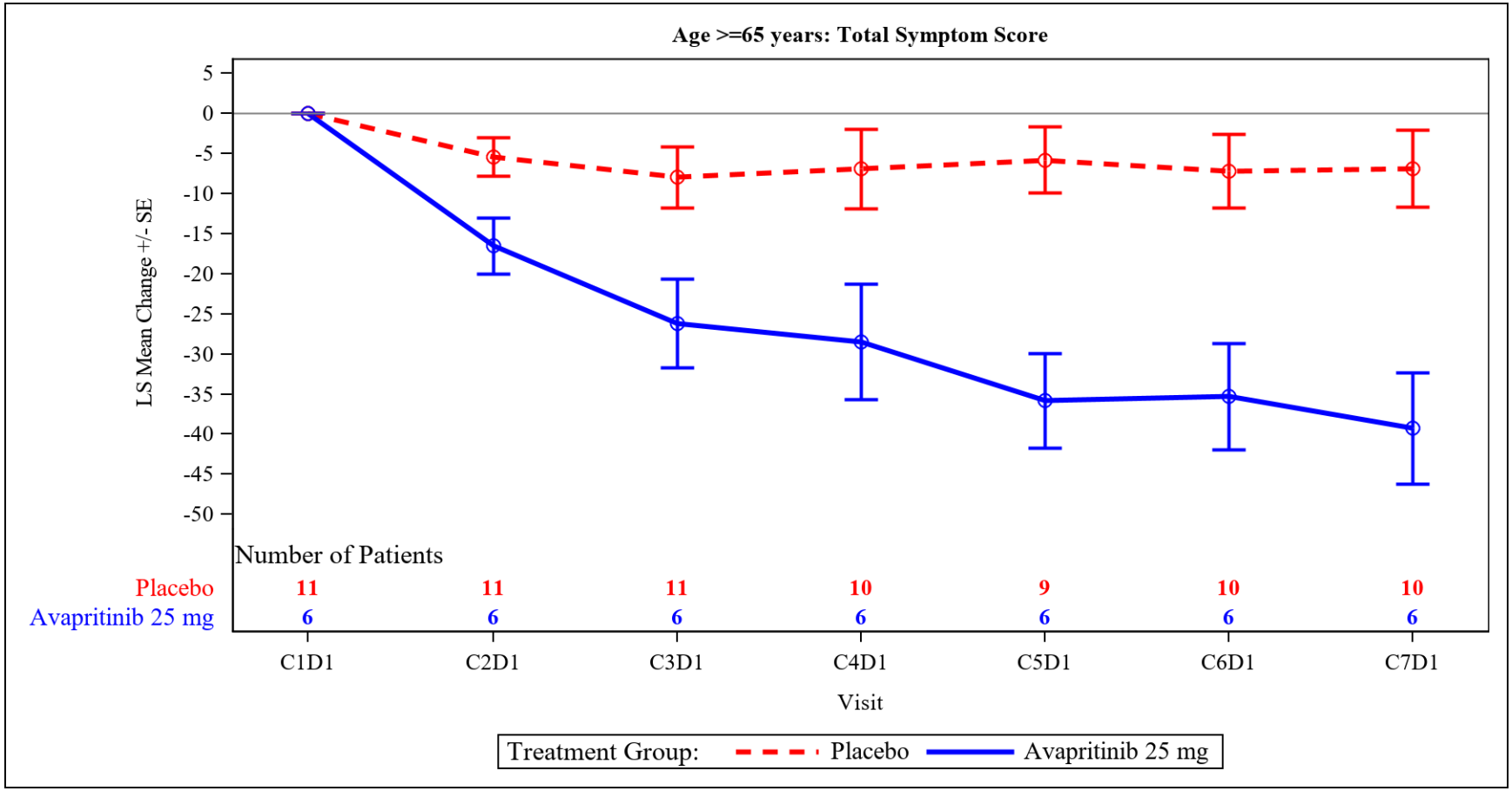
Figure 35.2.1.2.2.1a
LSMean Plot of Change from Baseline in TSS of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)



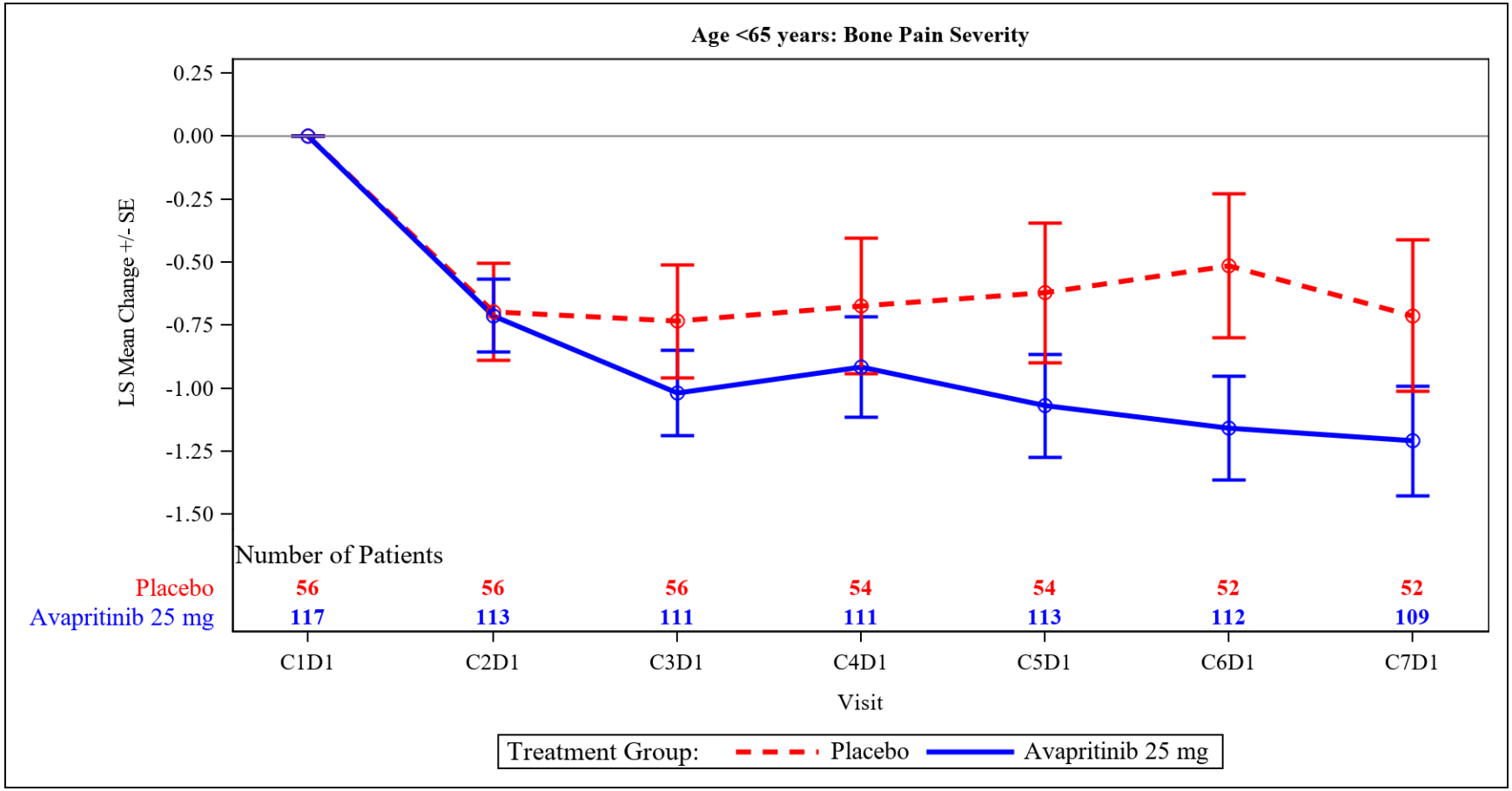
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-tss-sum-g-pp-age-a.sas Date: 16:15/07AUG2023

Figure 35.2.1.2.2.1a
LSMean Plot of Change from Baseline in TSS of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)



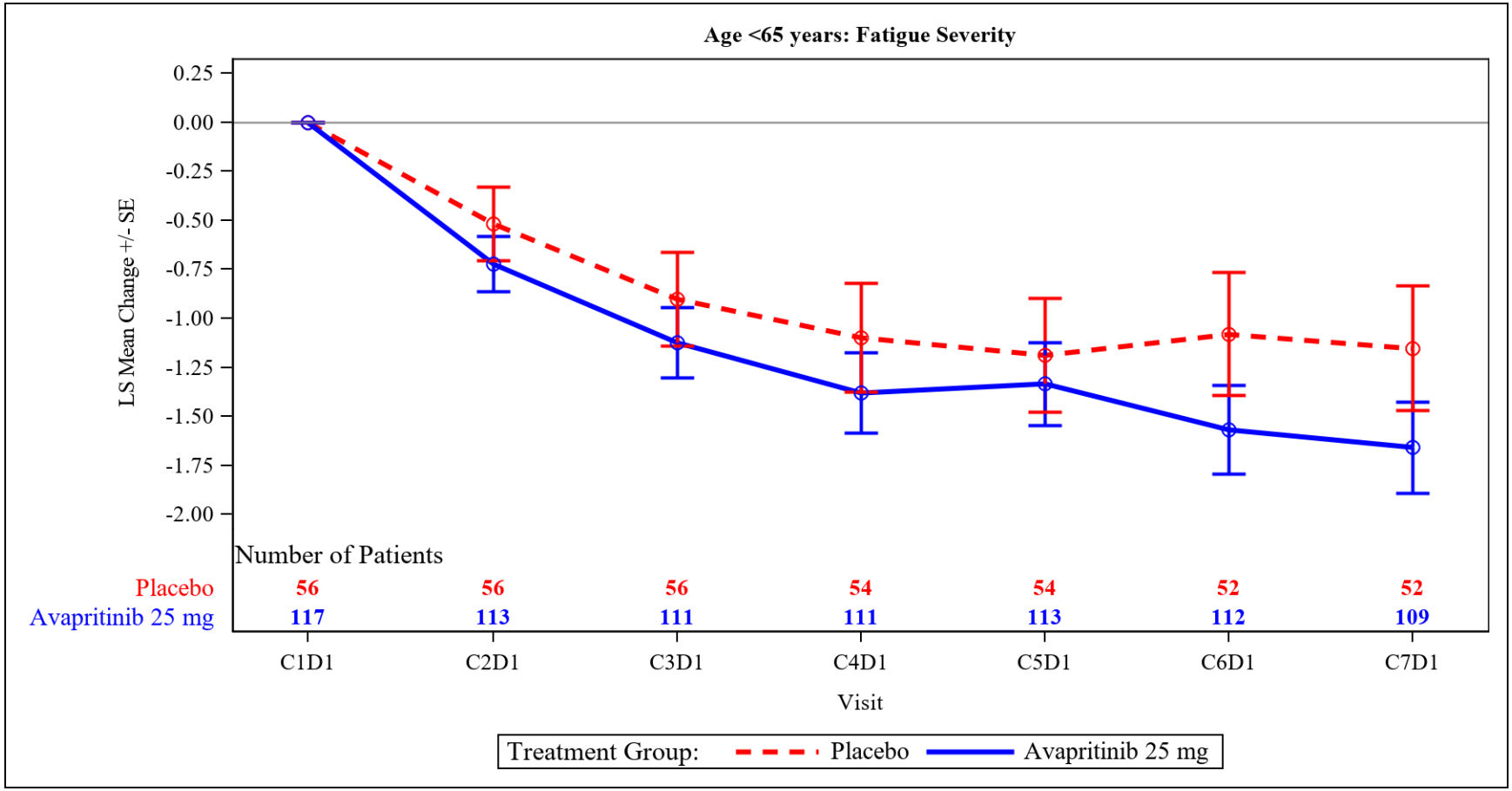
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-tss-sum-g-pp-age-a.sas Date: 16:15/07AUG2023

Figure 35.2.2.3.2.1a
LSMean Plot of Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)



Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-ismsaf-ind-sum-g-pp-age-a.sas Date: 16:24/07AUG2023

Figure 35.2.2.3.2.1a
LSMean Plot of Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)



Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-ismsaf-ind-sum-g-pp-age-a.sas Date: 16:24/07AUG2023

Figure 35.2.2.3.2.1a
LSMean Plot of Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

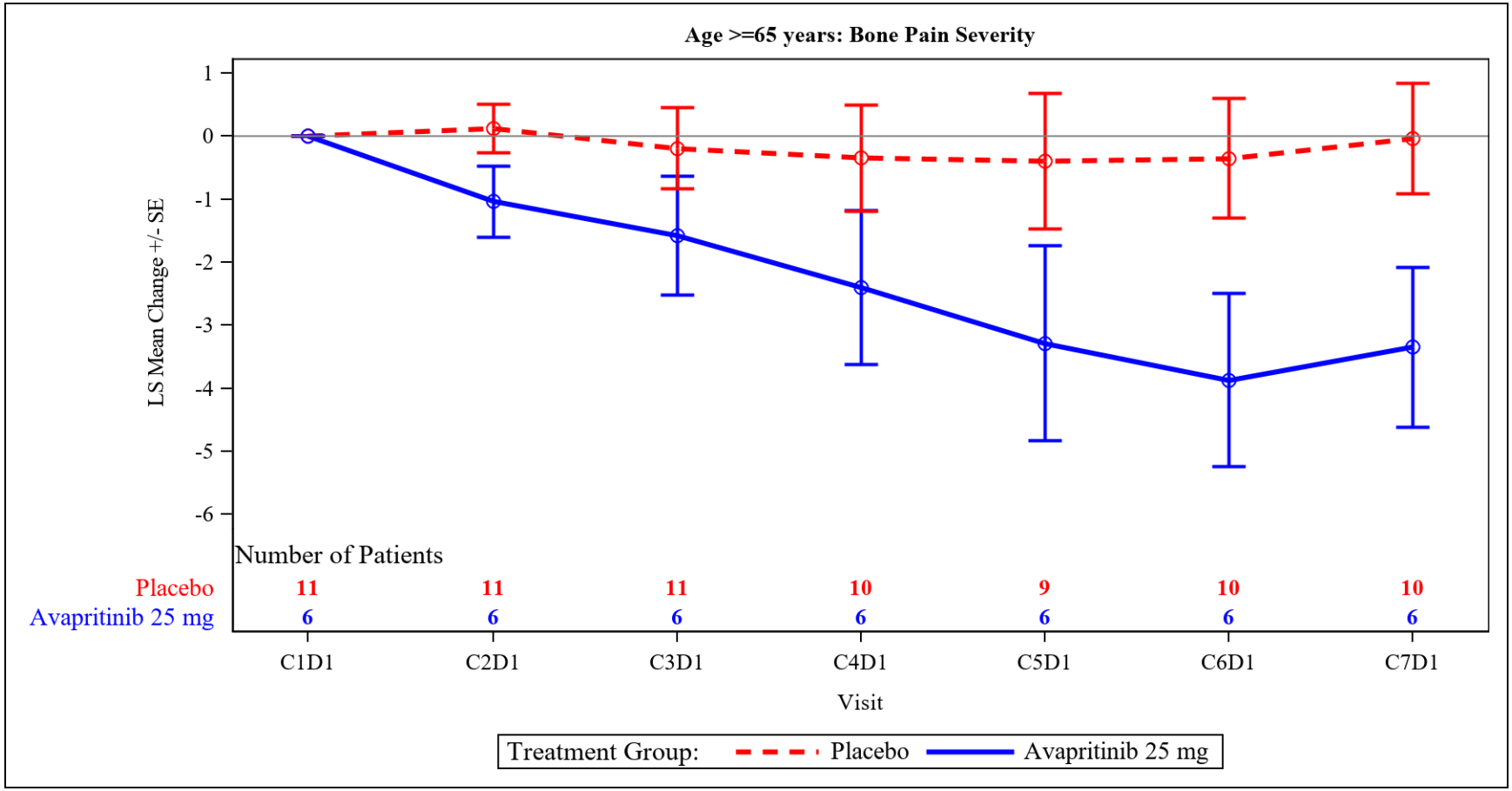


Figure 35.2.2.3.2.1a
LSMean Plot of Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

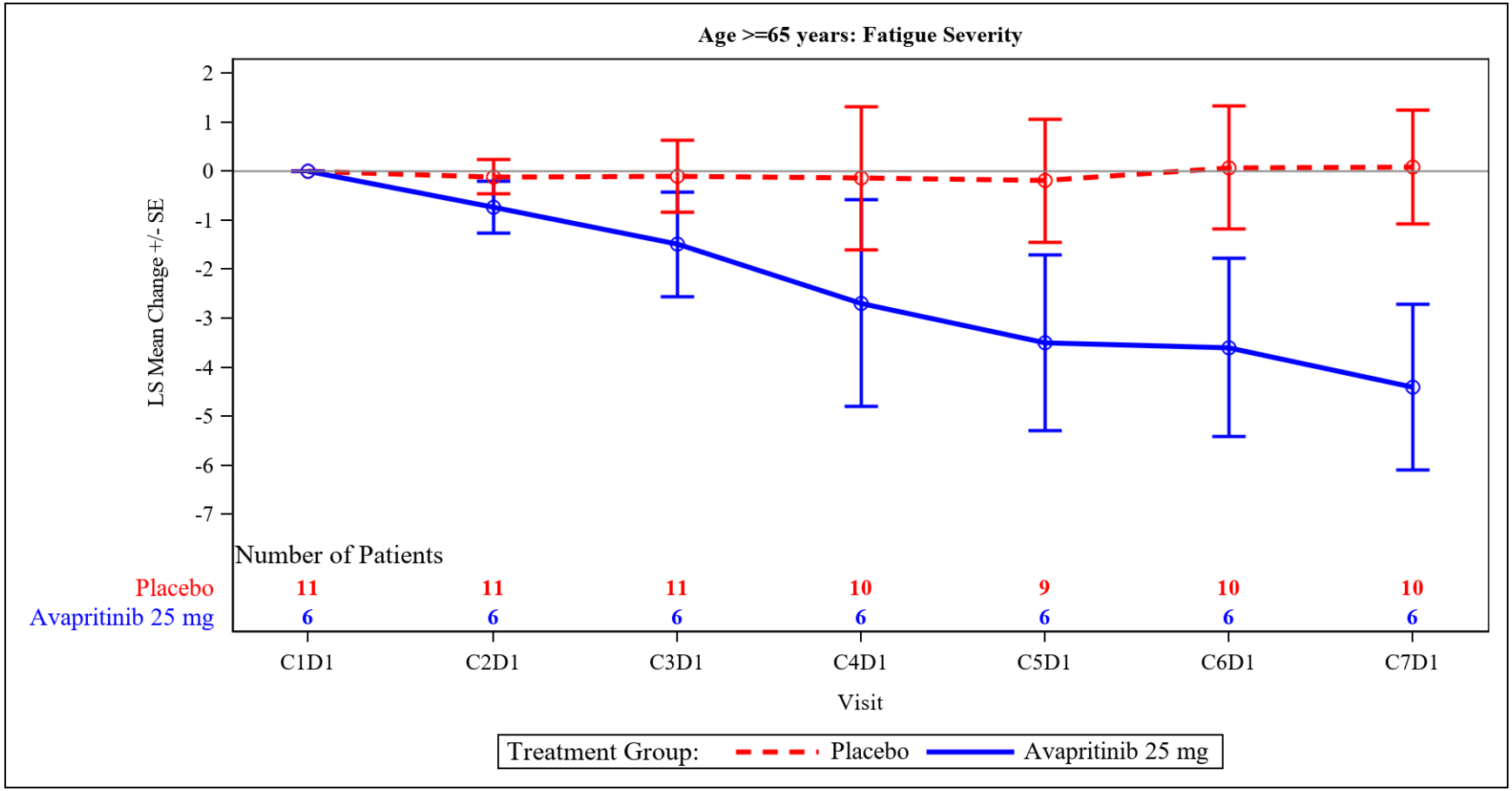


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Figure 35.2.2.4.2.2.1a
LSMean Plot of Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

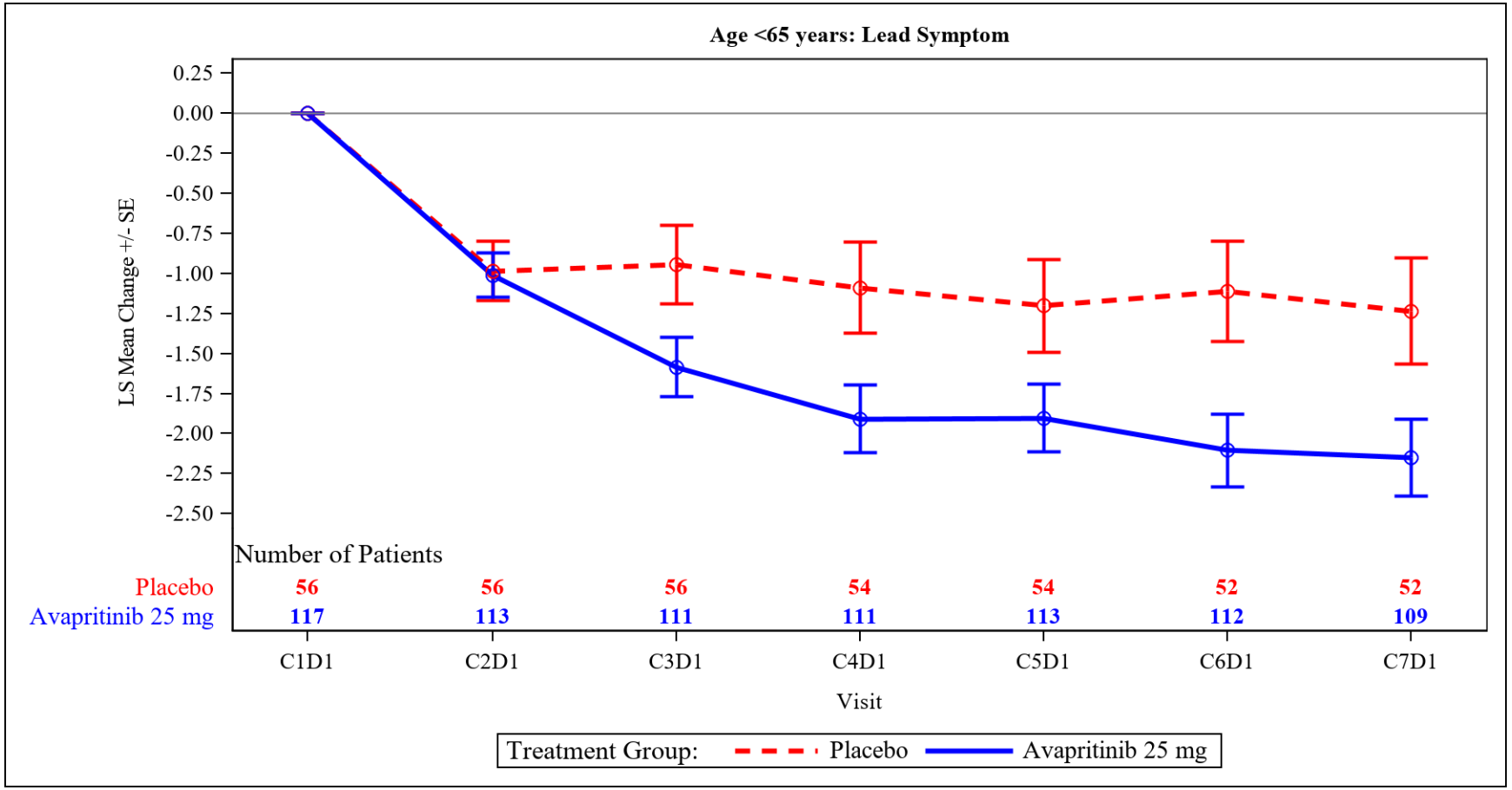

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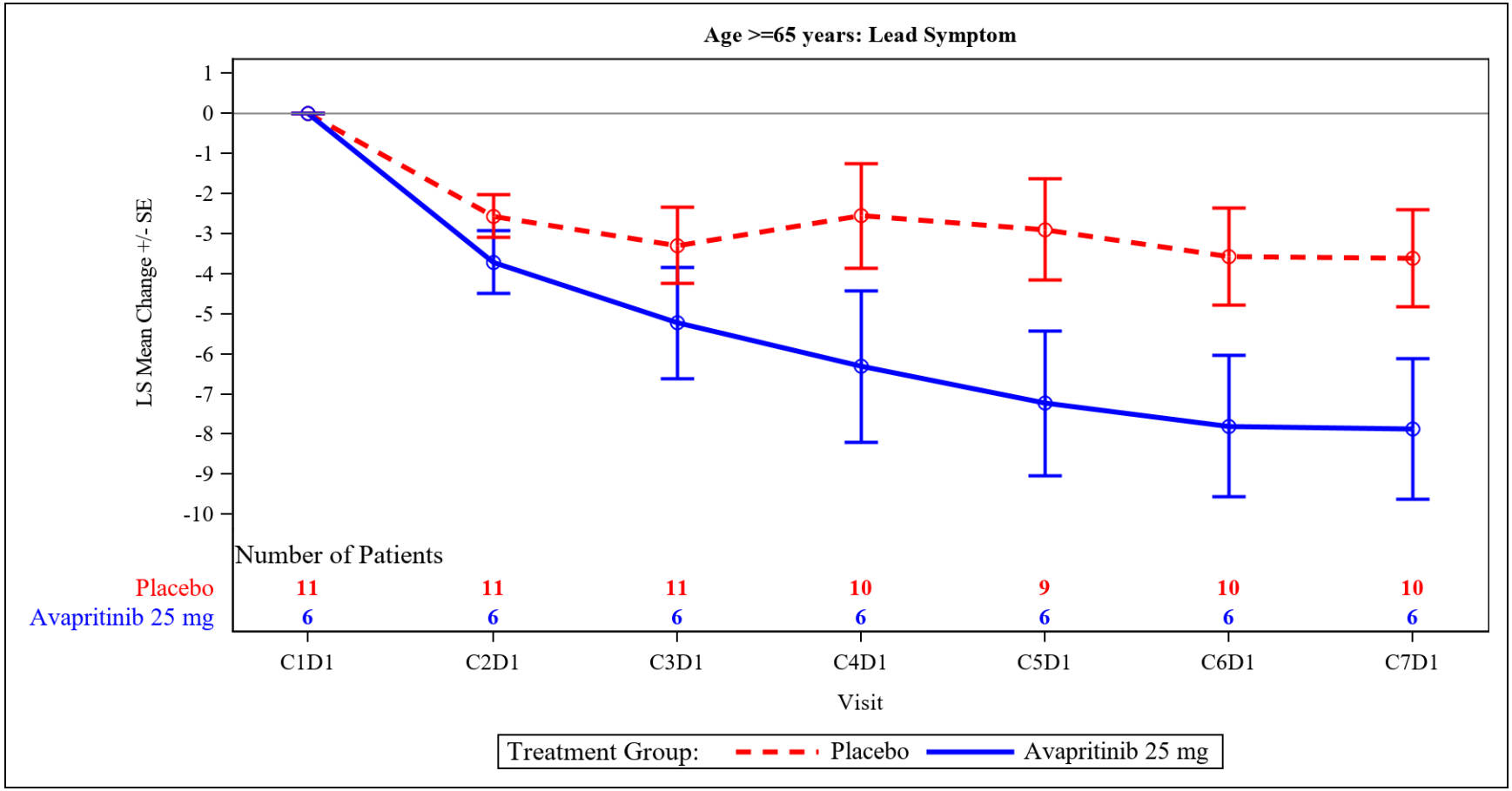
Figure 35.2.2.4.2.2.1a
LSMean Plot of Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)



Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-lead-sym-sum-g-pp-age-a.sas Date: 16:27/07AUG2023

Figure 35.2.2.4.4.2.1a
LSMean Plot of Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

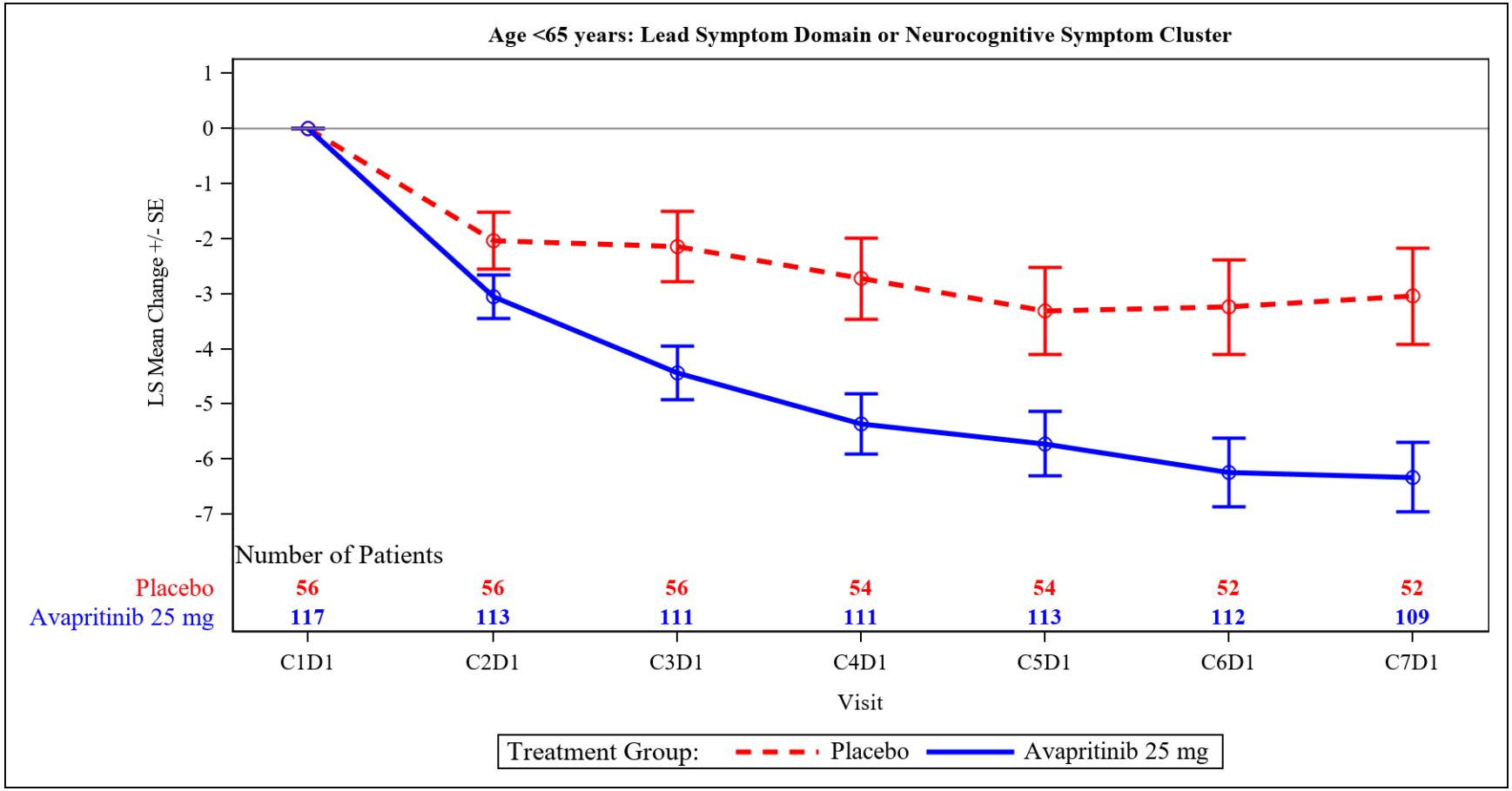


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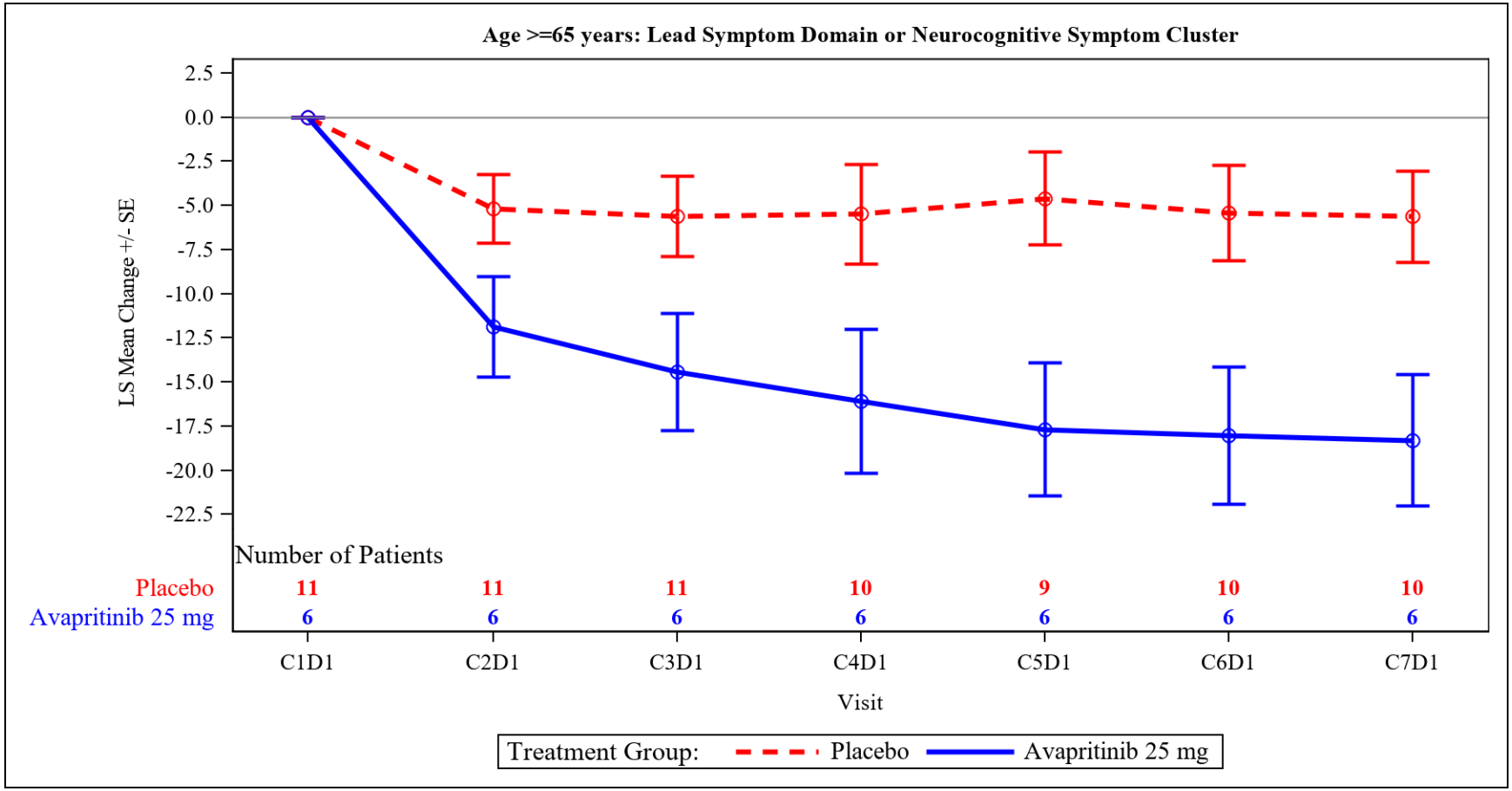
Figure 35.2.2.4.4.2.1a
LSMean Plot of Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)



Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-lead-sym-dom-sum-g-pp-age-a.sas Date: 16:27/07AUG2023

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Figure 35.2.3.2.2.1a
LSMean Plot of Change from Baseline in Serum Tryptase (ng/mL) by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

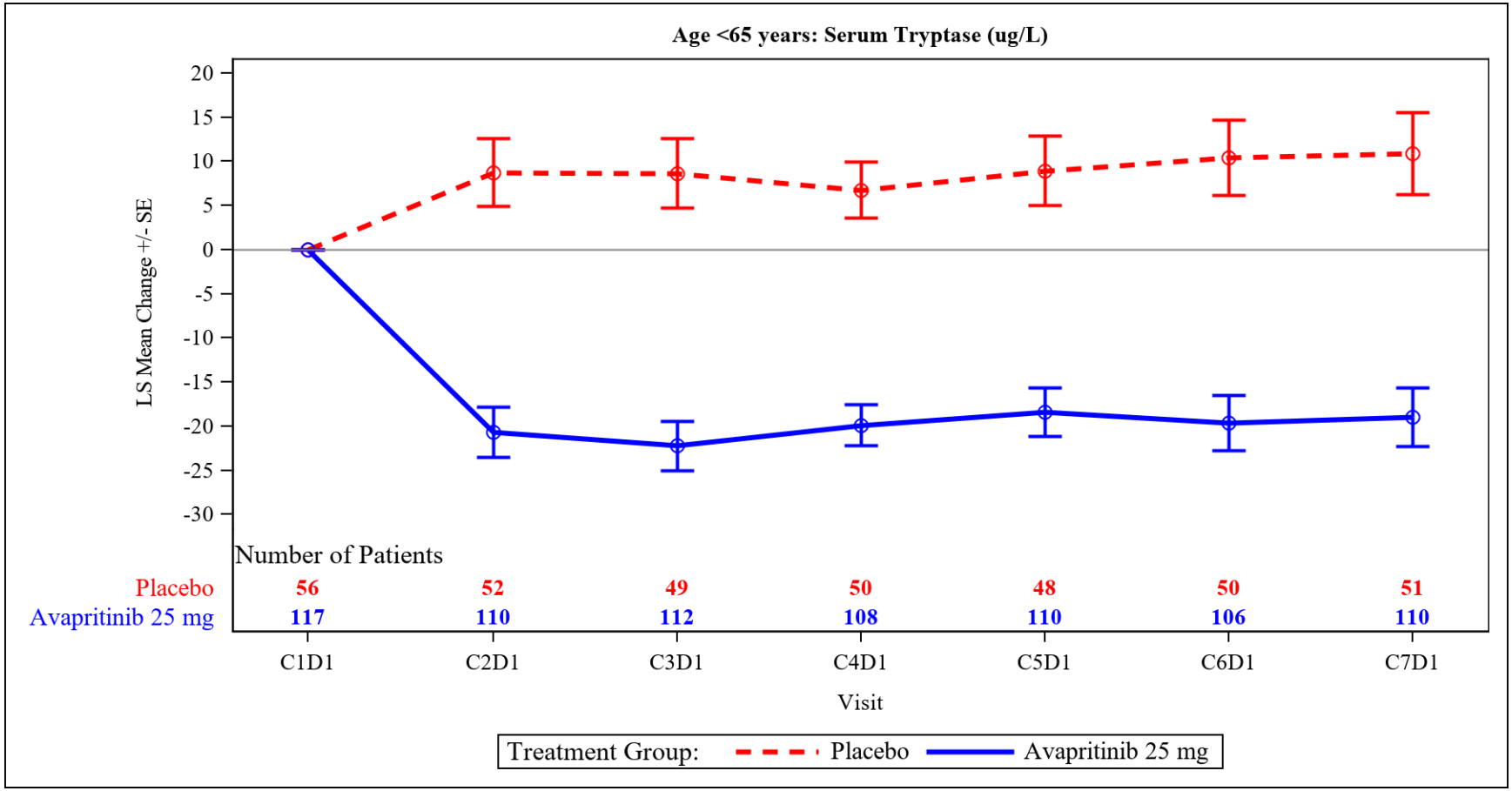

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Figure 35.2.3.2.2.1a
LSMean Plot of Change from Baseline in Serum Tryptase (ng/mL) by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

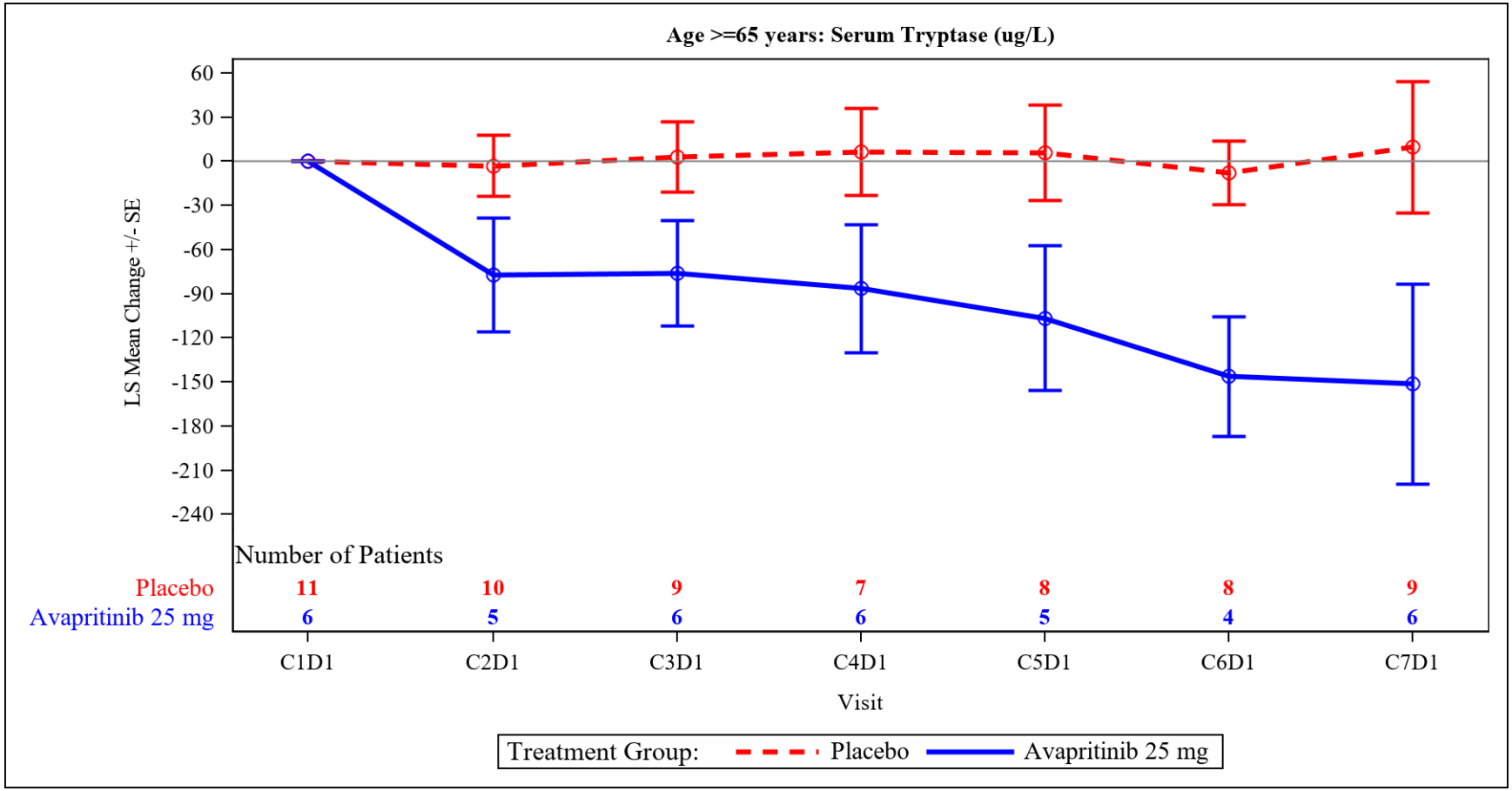

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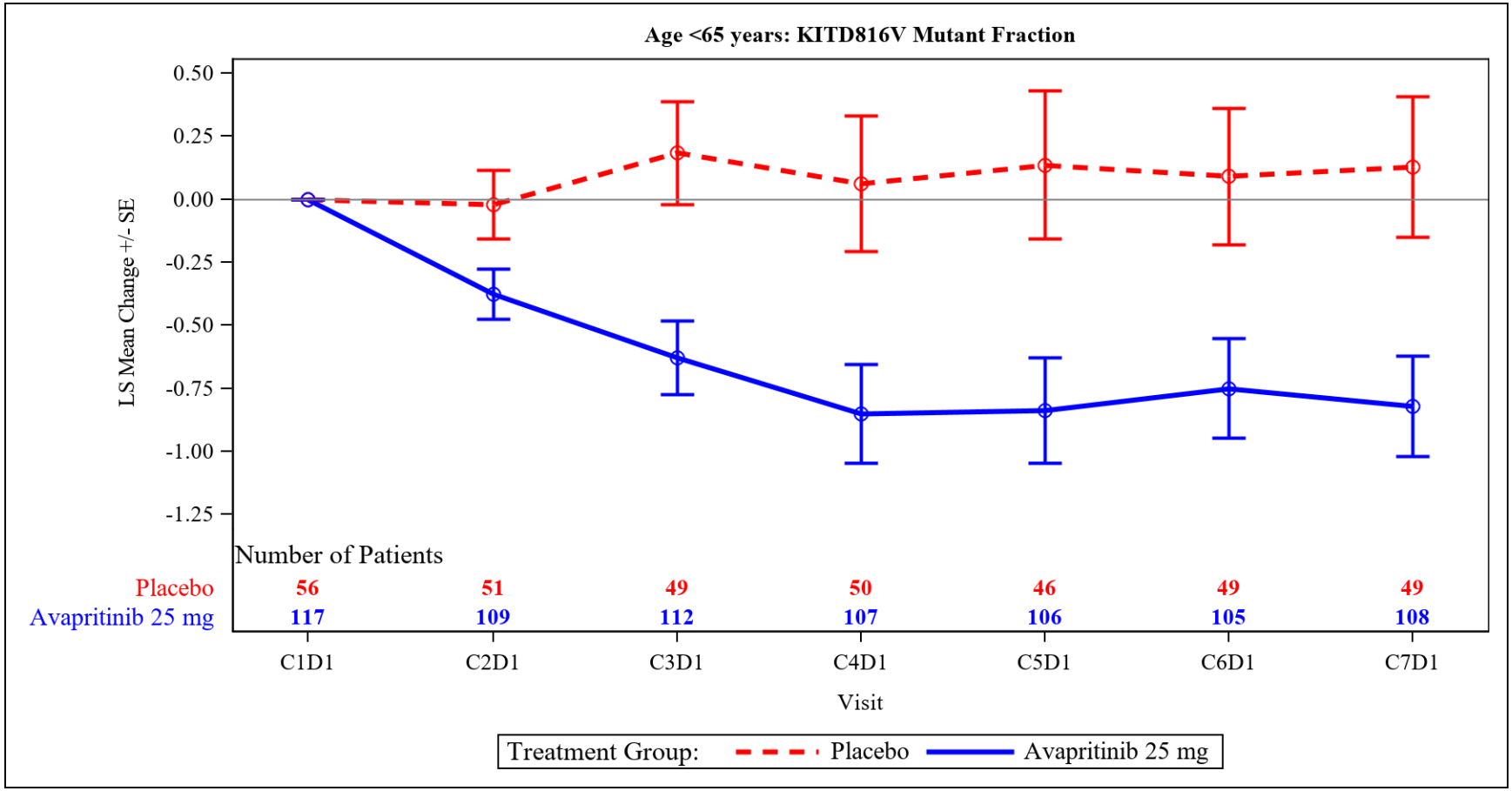
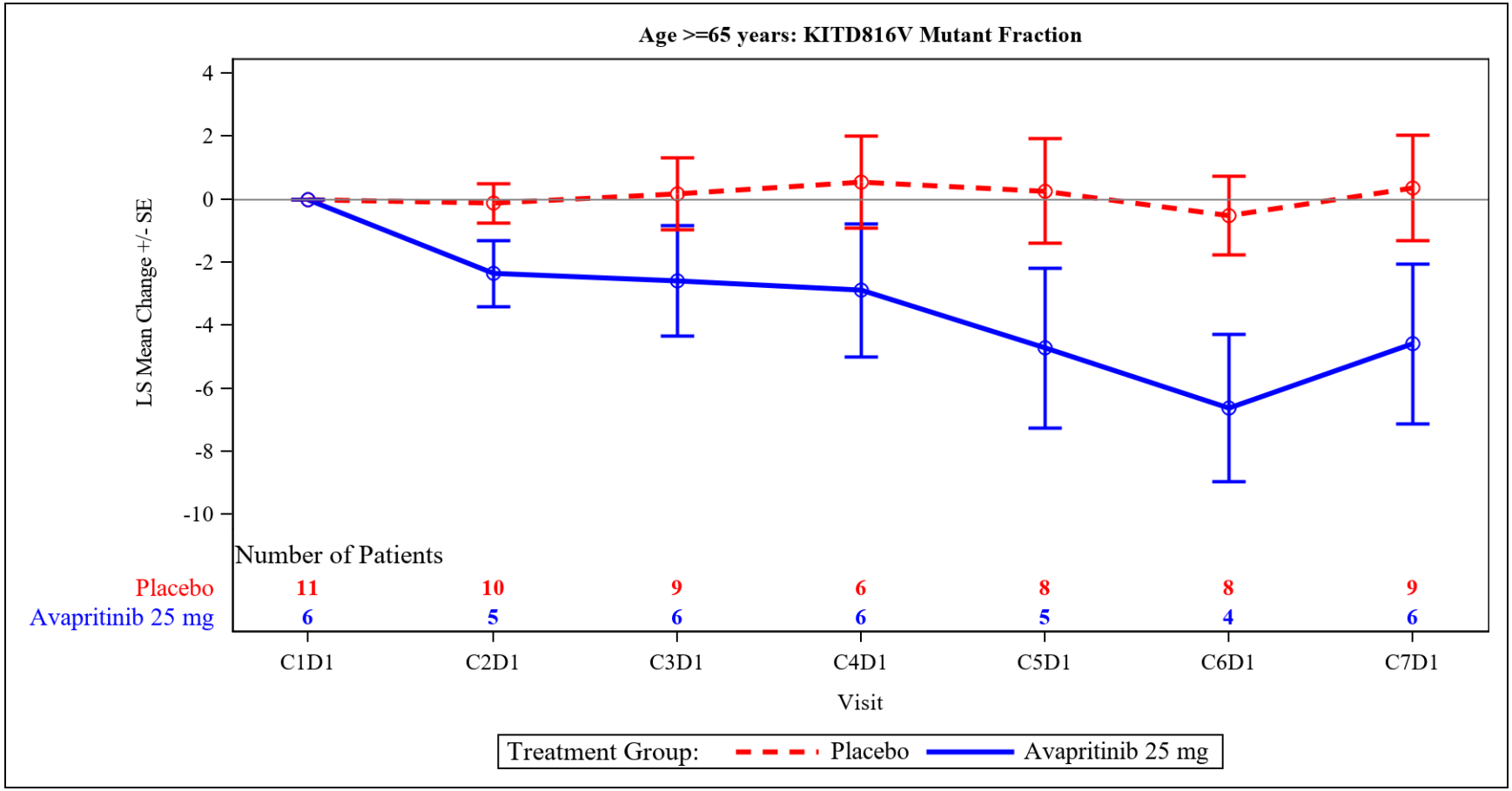
Figure 35.2.4.1.2.1a
LSMean Plot of Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)



Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-mut-sum-g-pp-age-a.sas Date: 16:30/07AUG2023

Figure 35.2.4.1.2.1a
LSMean Plot of Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)



Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-mut-sum-g-pp-age-a.sas Date: 16:30/07AUG2023

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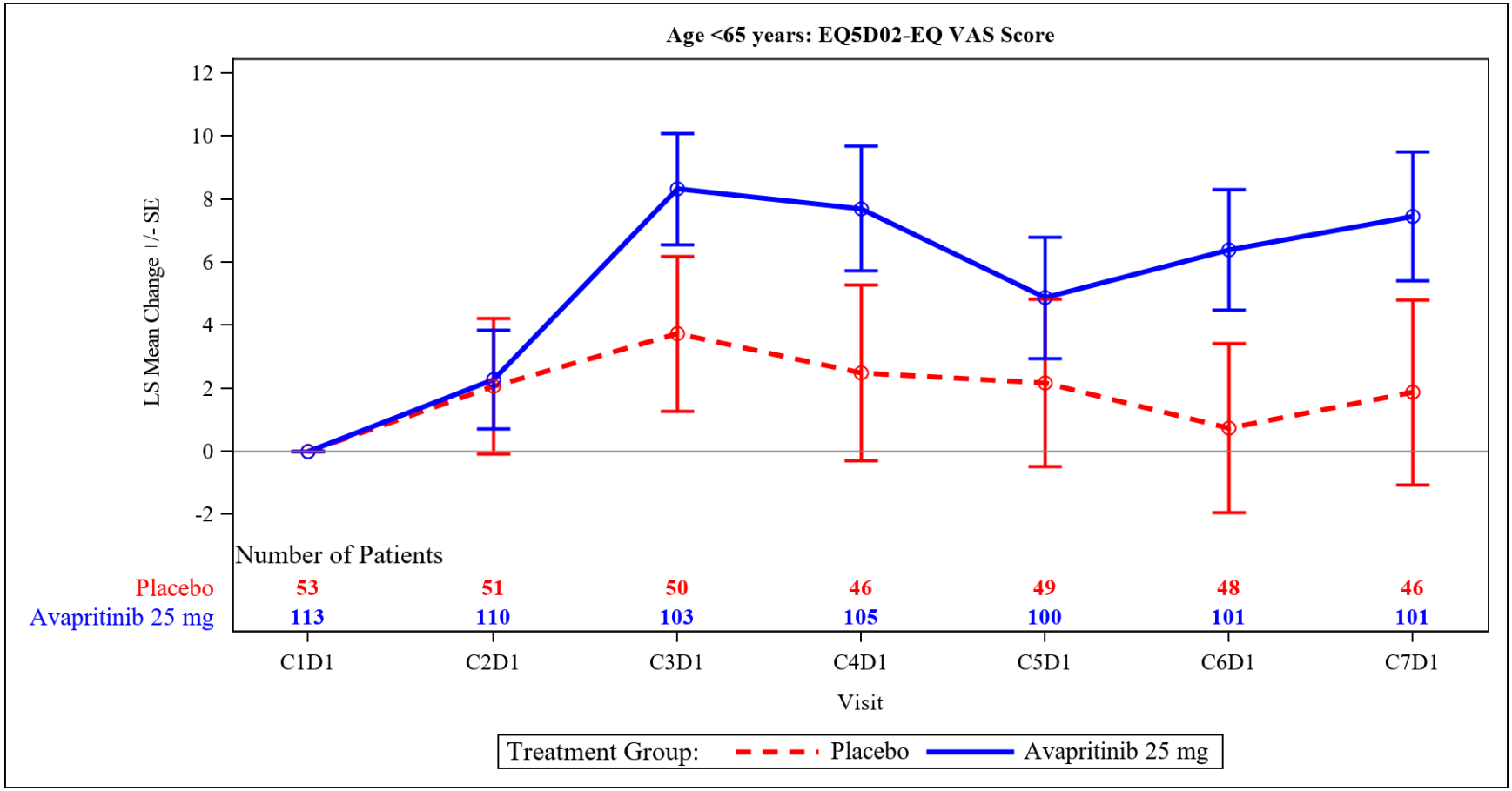
Figure 35.2.9.2.2.1a
LSMean Plot of Change from Baseline of EQ-5D-5L VAS by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)



Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-eq5d-vas-g-pp-age-a.sas
Date: 16:31/07AUG2023

Figure 35.2.9.2.2.1a
LSMean Plot of Change from Baseline of EQ-5D-5L VAS by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

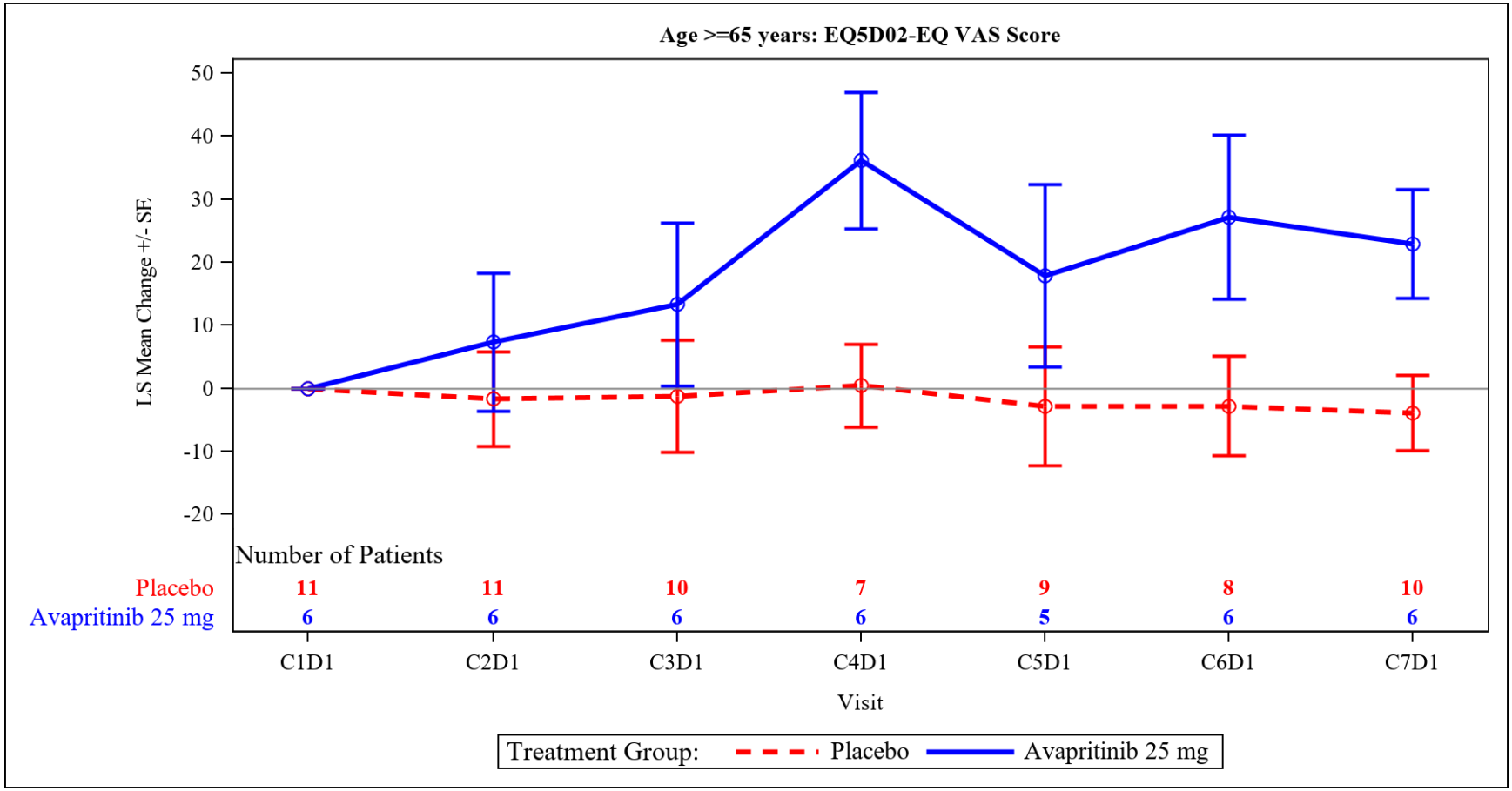


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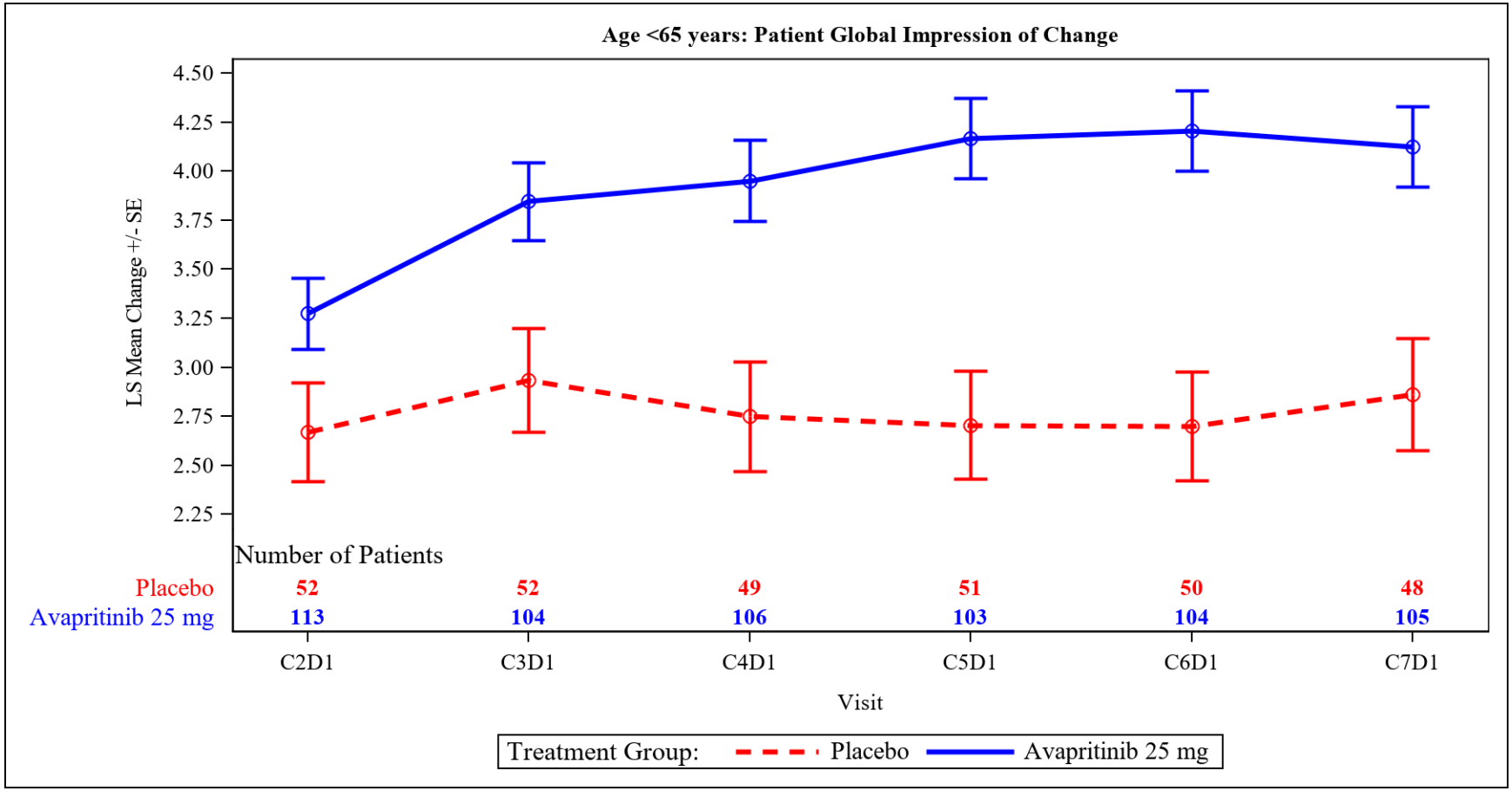
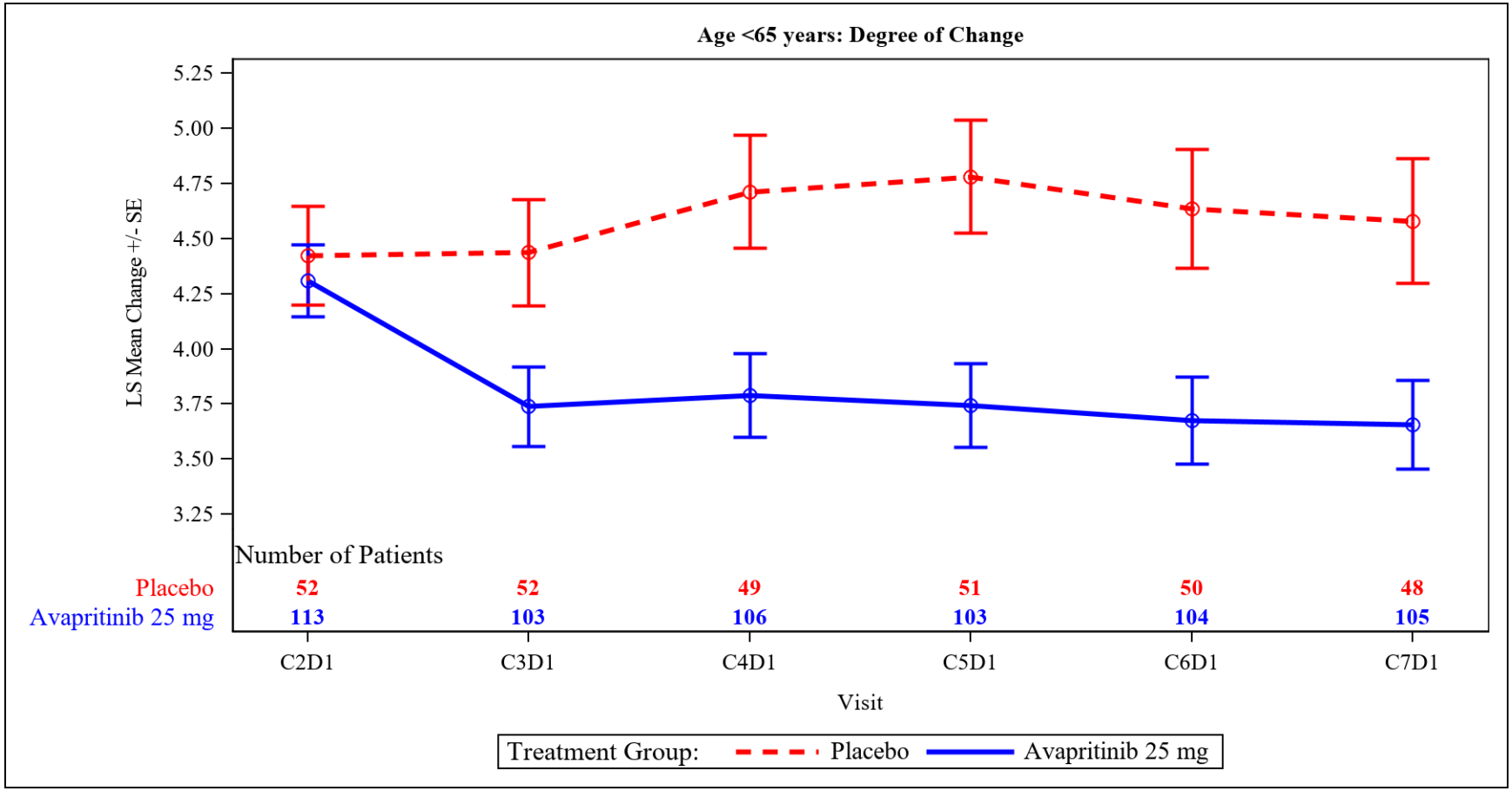
Figure 35.2.7.2.1a
LSMean Plot of PGIC by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)



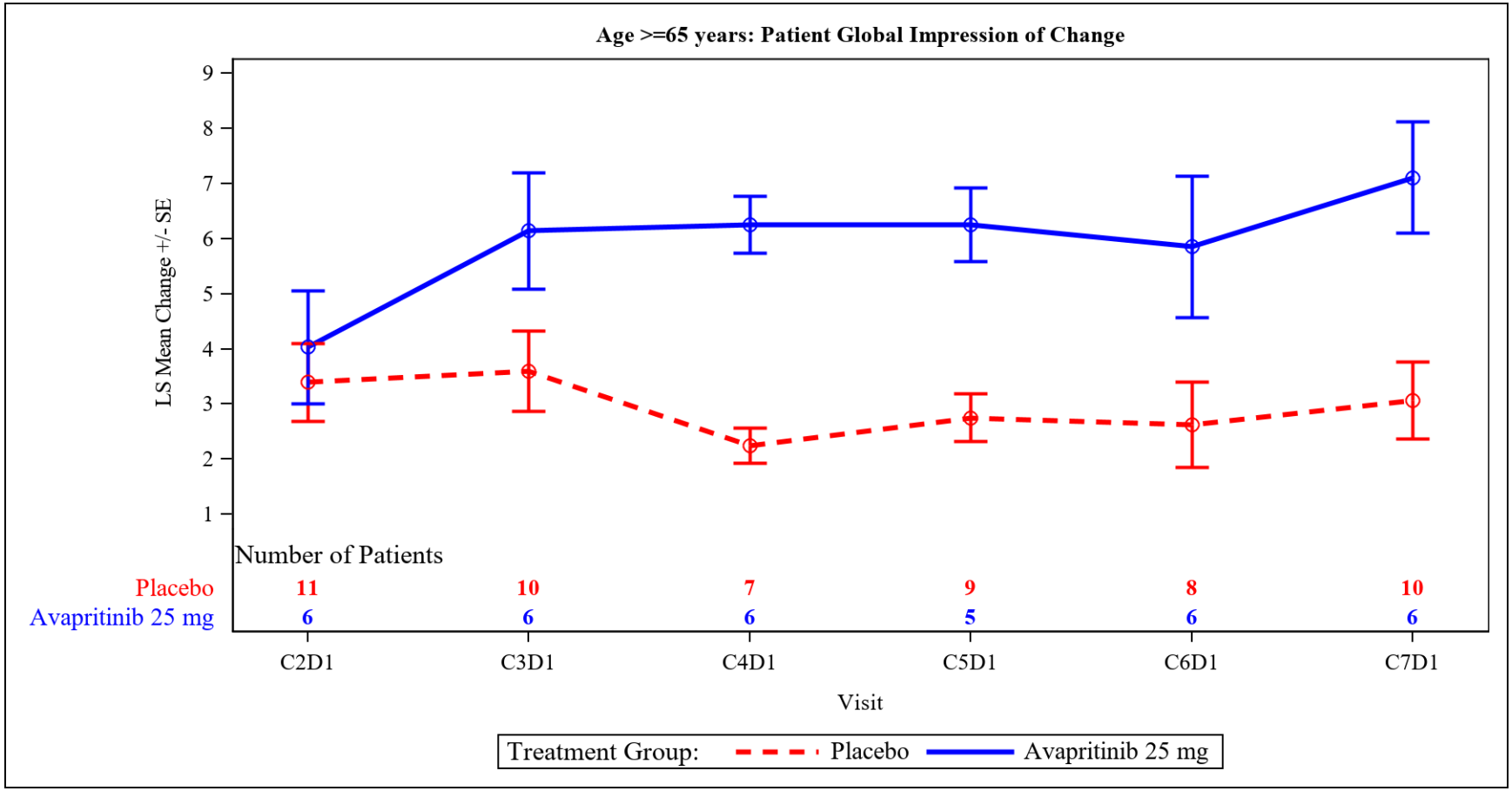
Patient Global Impression of Change Scale: 1=No change, 2=Almost the same, 3=A little better, 4=Somewhat better, 5=Moderately Better, 6=Better, 7=A great deal better.
Degree of Change is in the range of 0 to 10, with 0 = much better and 10 = much worse.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-pgic-sum-g-pp-age-a.sas Date: 16:31/07AUG2023

Figure 35.2.7.2.1a
LSMean Plot of PGIC by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)



Patient Global Impression of Change Scale: 1=No change, 2=Almost the same, 3=A little better, 4=Somewhat better, 5=Moderately Better, 6=Better, 7=A great deal better.
Degree of Change is in the range of 0 to 10, with 0 = much better and 10 = much worse.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-pgic-sum-g-pp-age-a.sas Date: 16:31/07AUG2023

Figure 35.2.7.2.1a
LSMean Plot of PGIC by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)



Patient Global Impression of Change Scale: 1=No change, 2=Almost the same, 3=A little better, 4=Somewhat better, 5=Moderately Better, 6=Better, 7=A great deal better.
Degree of Change is in the range of 0 to 10, with 0 = much better and 10 = much worse.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-pgic-sum-g-pp-age-a.sas Date: 16:31/07AUG2023

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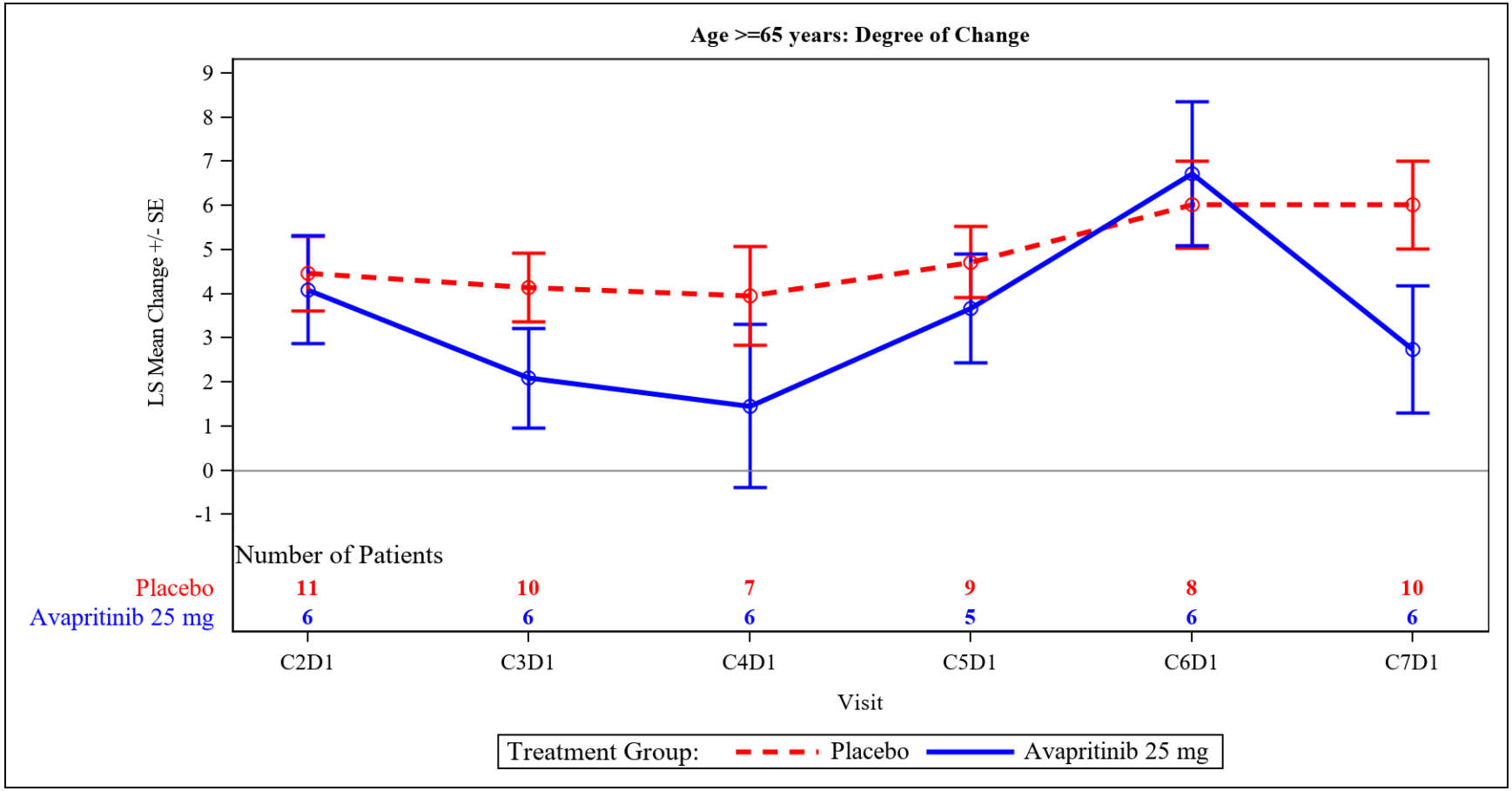
Figure 35.2.7.2.1a
LSMean Plot of PGIC by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)



Patient Global Impression of Change Scale: 1=No change, 2=Almost the same, 3=A little better, 4=Somewhat better, 5=Moderately Better, 6=Better, 7=A great deal better.
Degree of Change is in the range of 0 to 10, with 0 = much better and 10 = much worse.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-pgic-sum-g-pp-age-a.sas Date: 16:31/07AUG2023

Figure 35.2.8.2.1a
LSMean Plot of Change from Baseline in MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

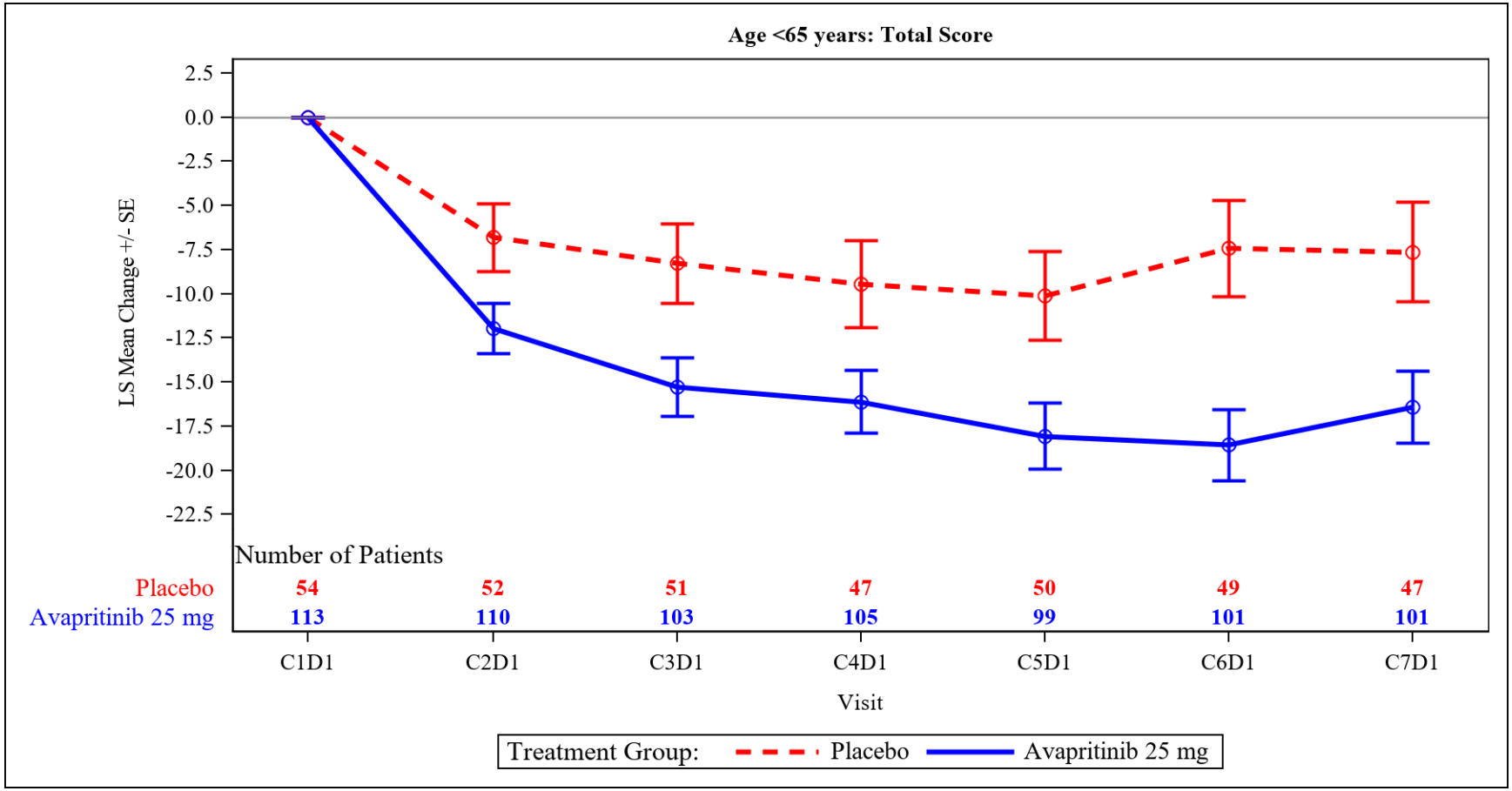
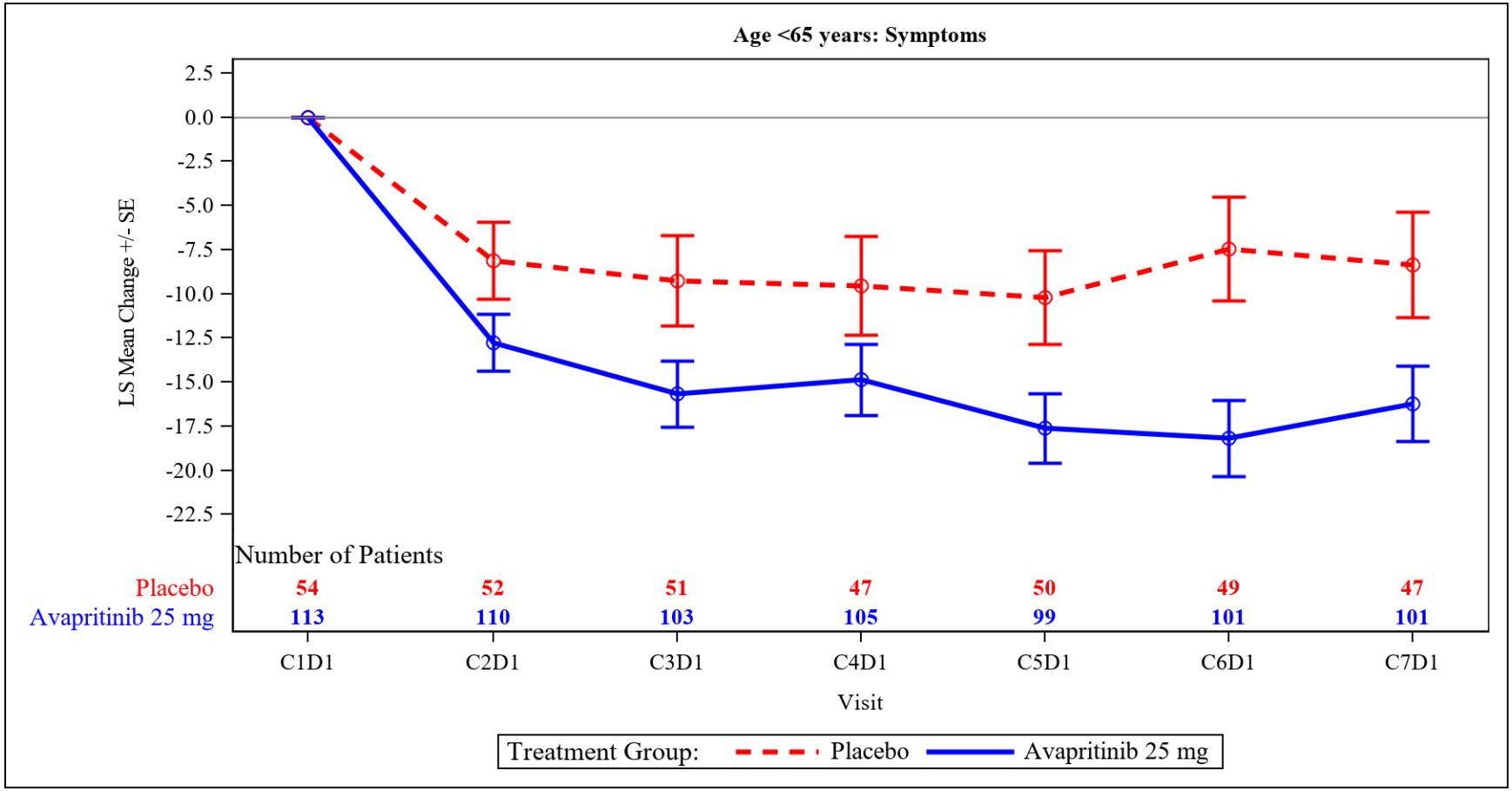


Figure 35.2.8.2.1a
LSMean Plot of Change from Baseline in MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)



Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-mcqol-sum-g-pp-age-a.sas Date: 16:31/07AUG2023

Figure 35.2.8.2.1a
LSMean Plot of Change from Baseline in MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

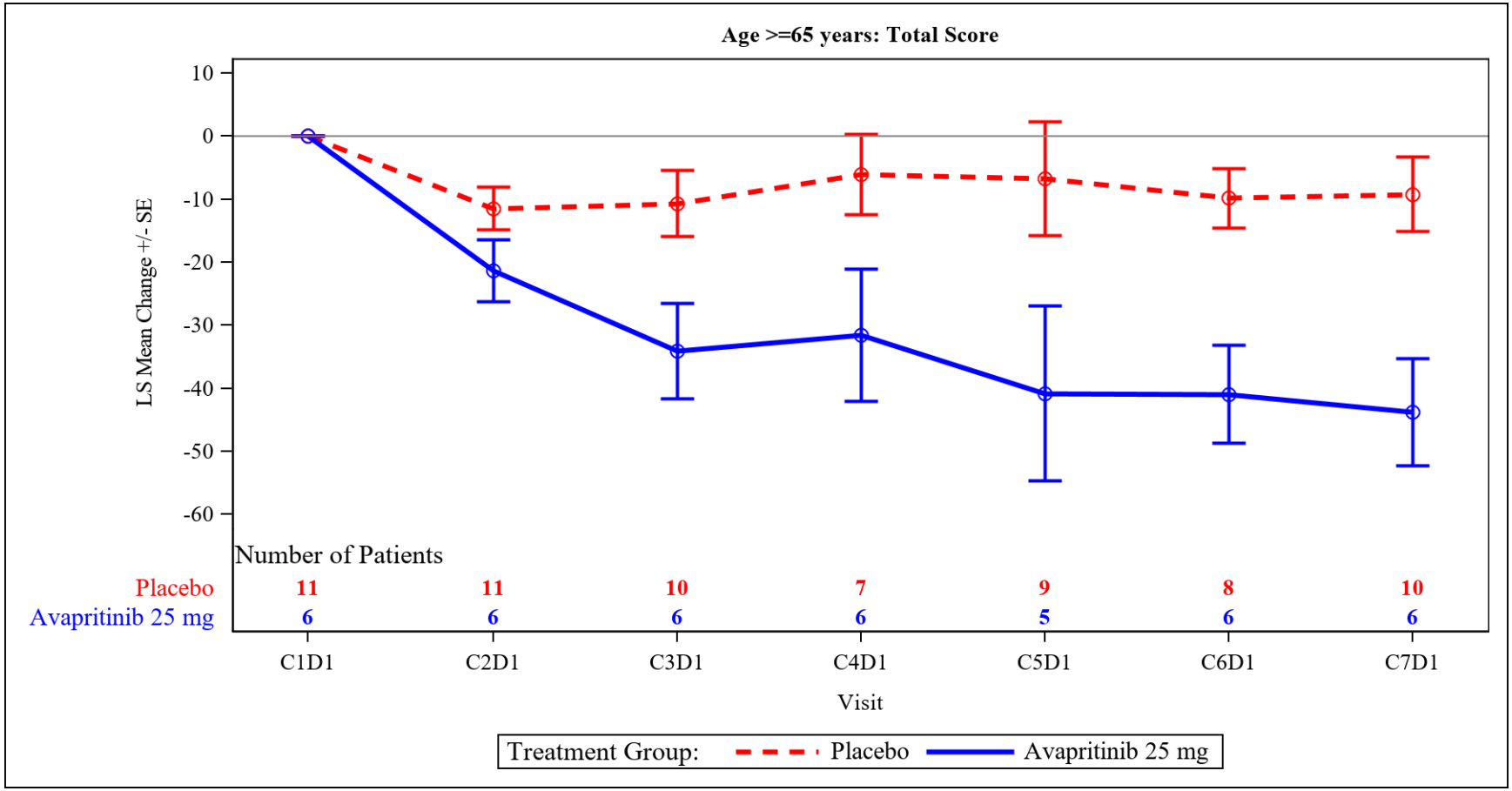


Figure 35.2.8.2.1a
LSMean Plot of Change from Baseline in MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

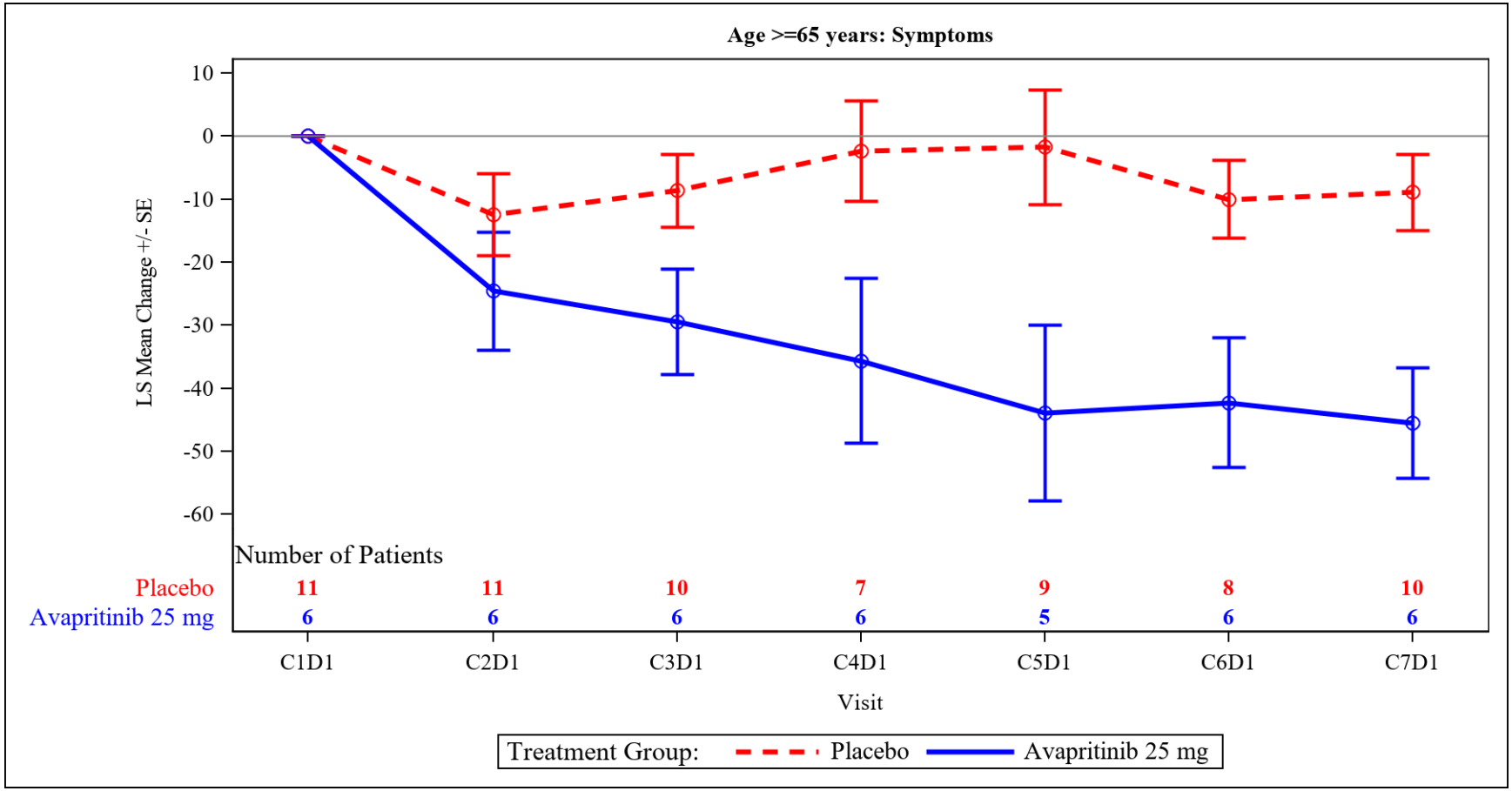


Figure 35.2.12.2.1a
LSMean Plot of Change from Baseline in Individual MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

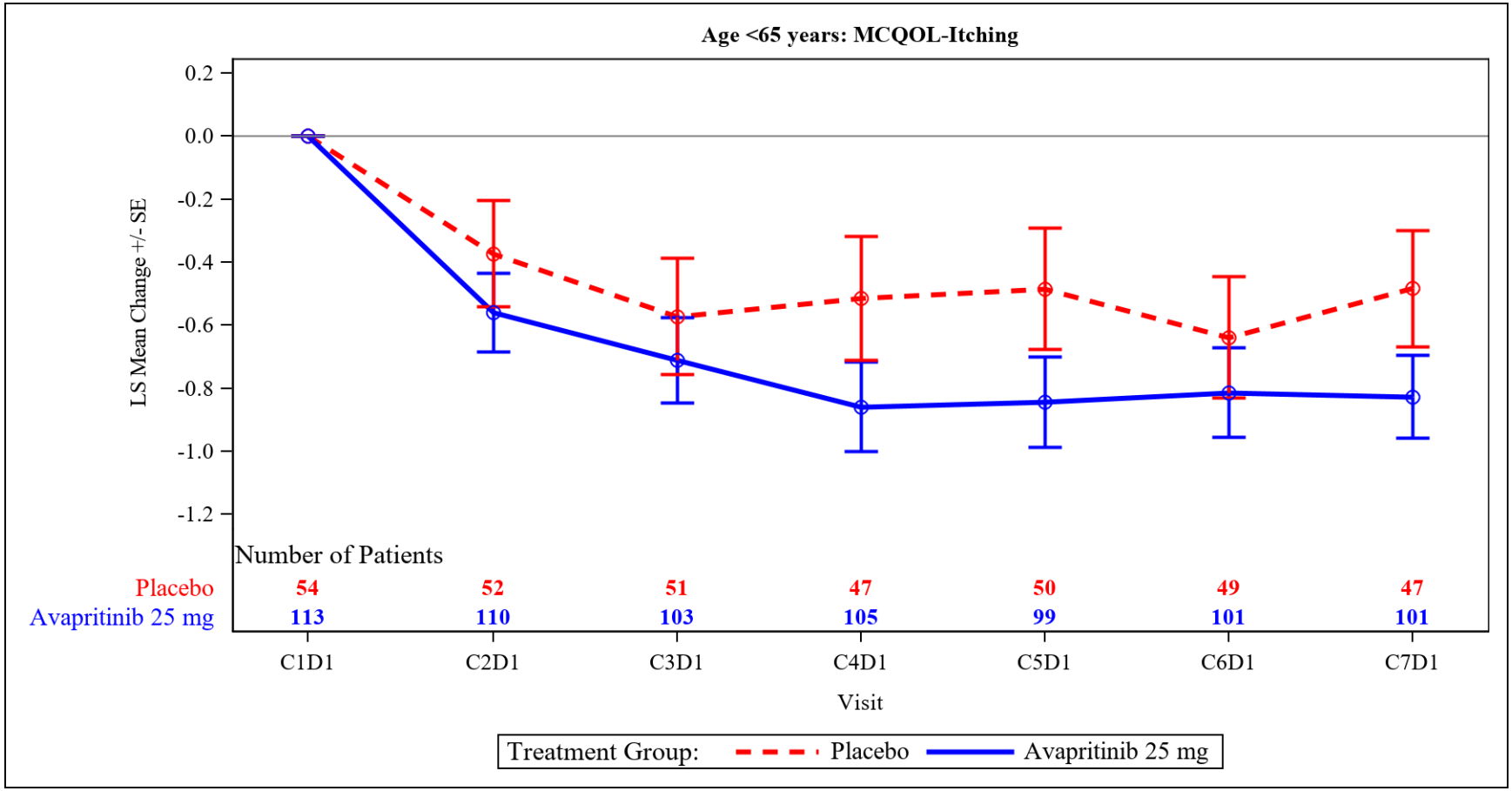


Figure 35.2.12.2.1a
LSMean Plot of Change from Baseline in Individual MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

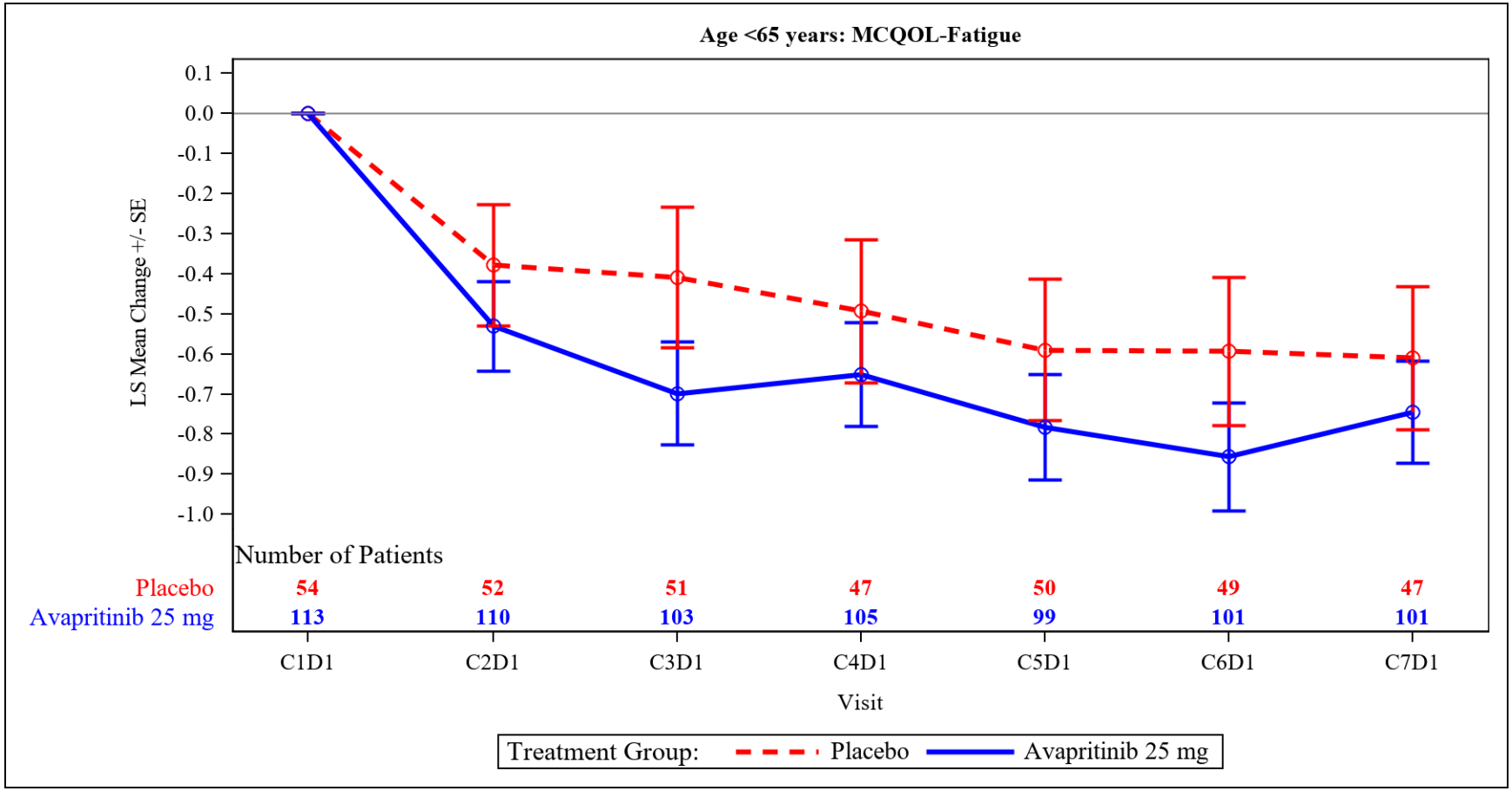


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Figure 35.2.12.2.1a
LSMean Plot of Change from Baseline in Individual MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

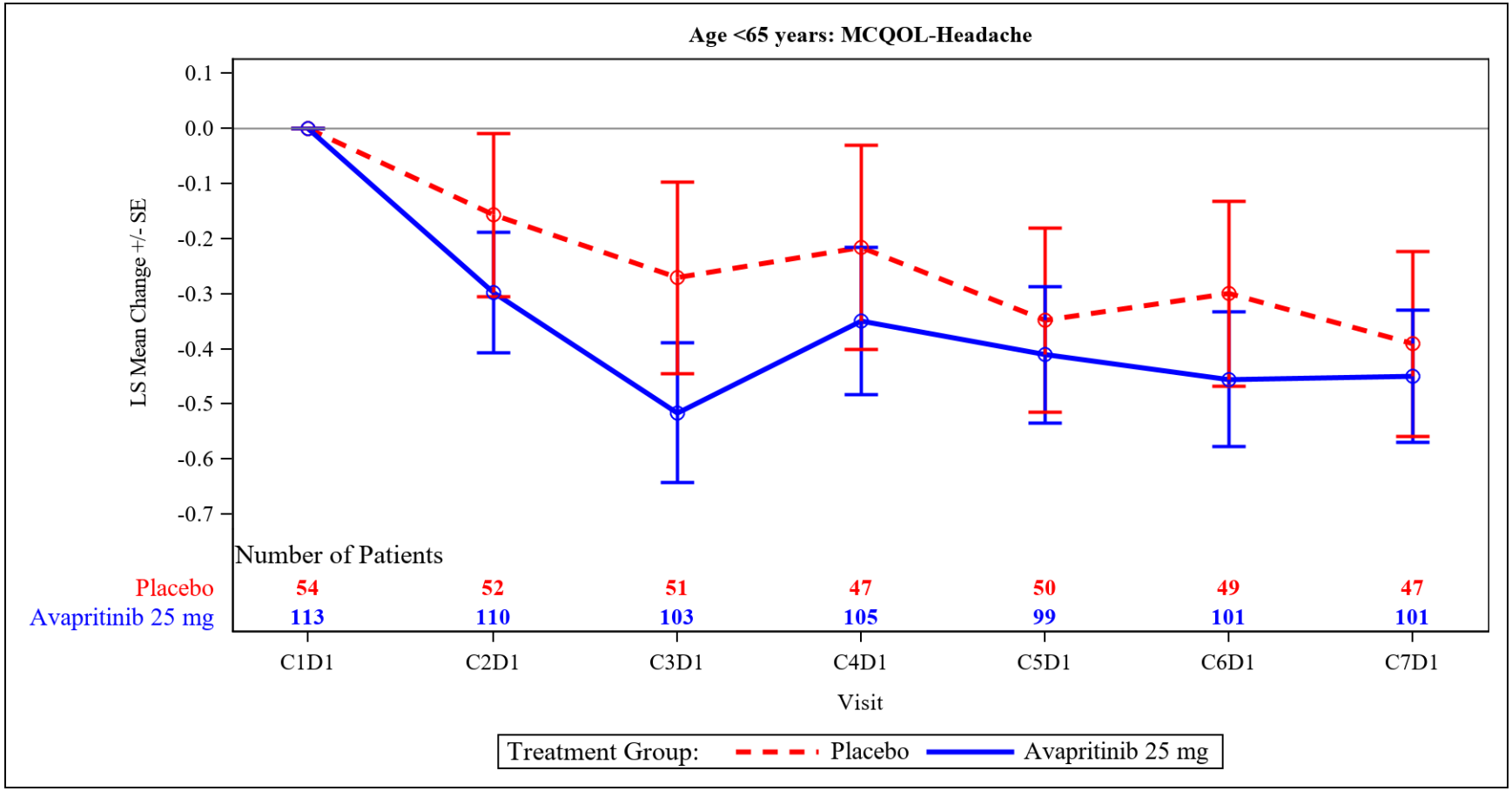

Figure 35.2.12.2.1a
LSMean Plot of Change from Baseline in Individual MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

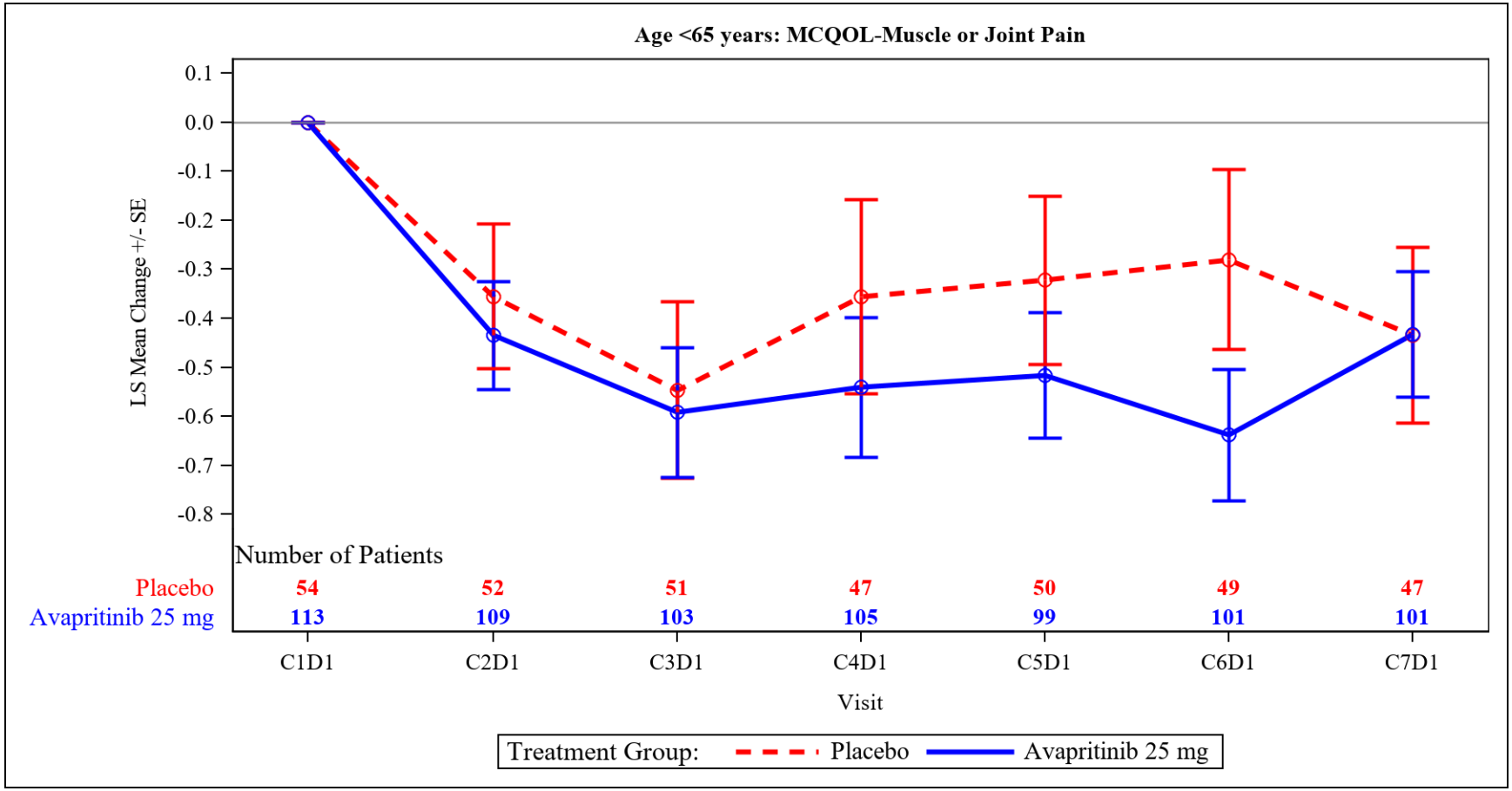

Figure 35.2.12.2.1a
LSMean Plot of Change from Baseline in Individual MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

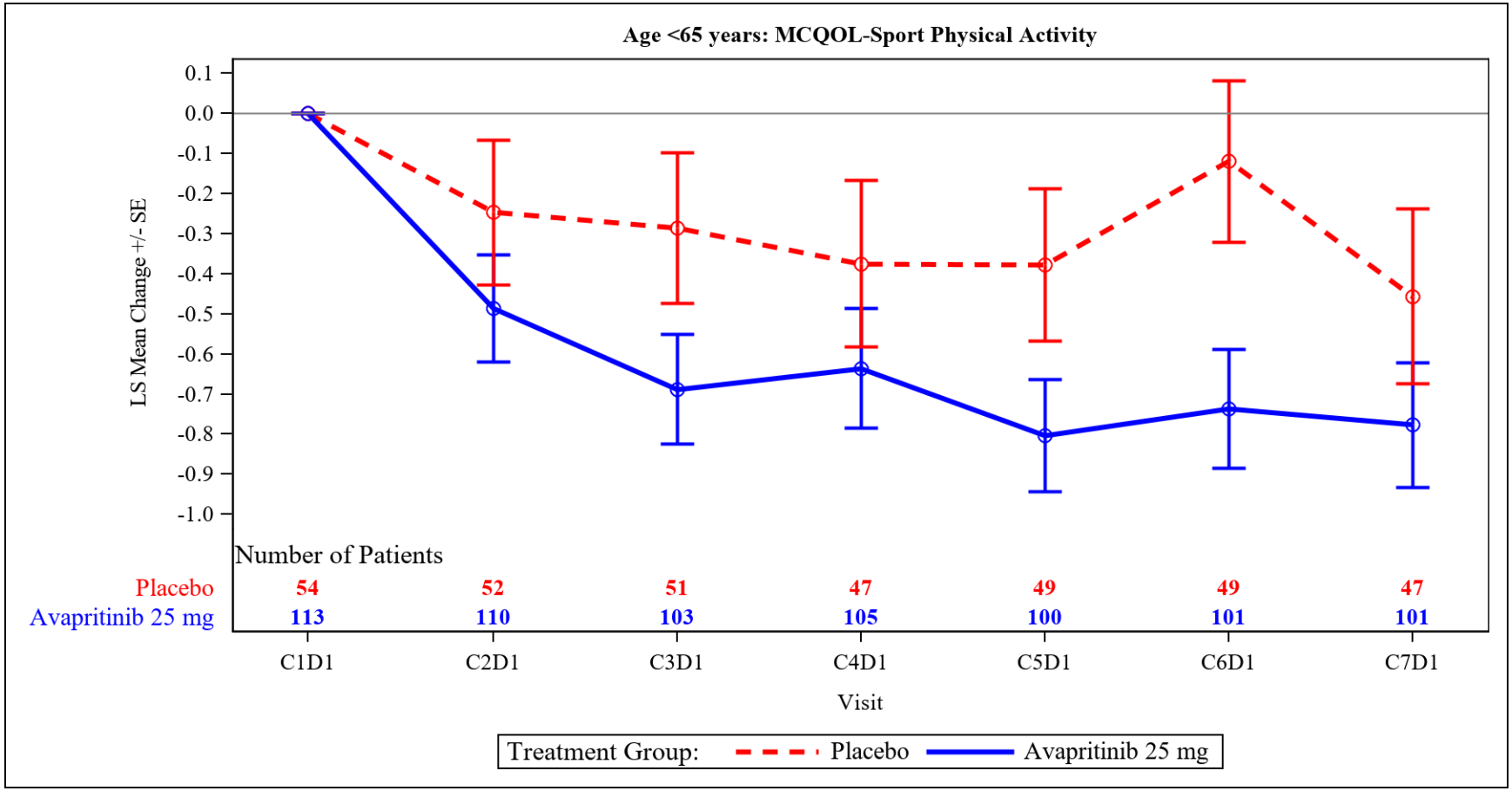

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Figure 35.2.12.2.1a
LSMean Plot of Change from Baseline in Individual MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

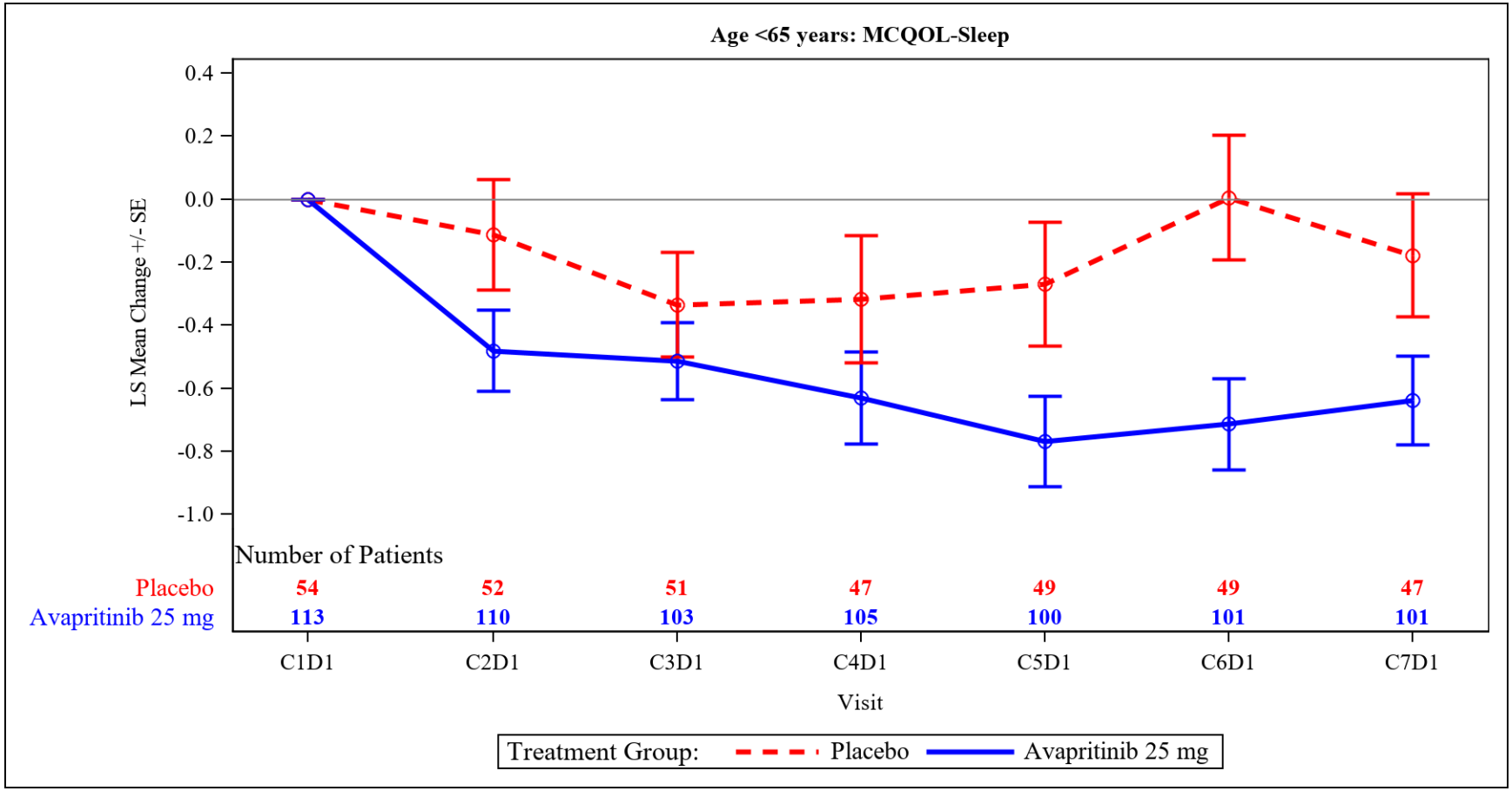

Figure 35.2.12.2.1a
LSMean Plot of Change from Baseline in Individual MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

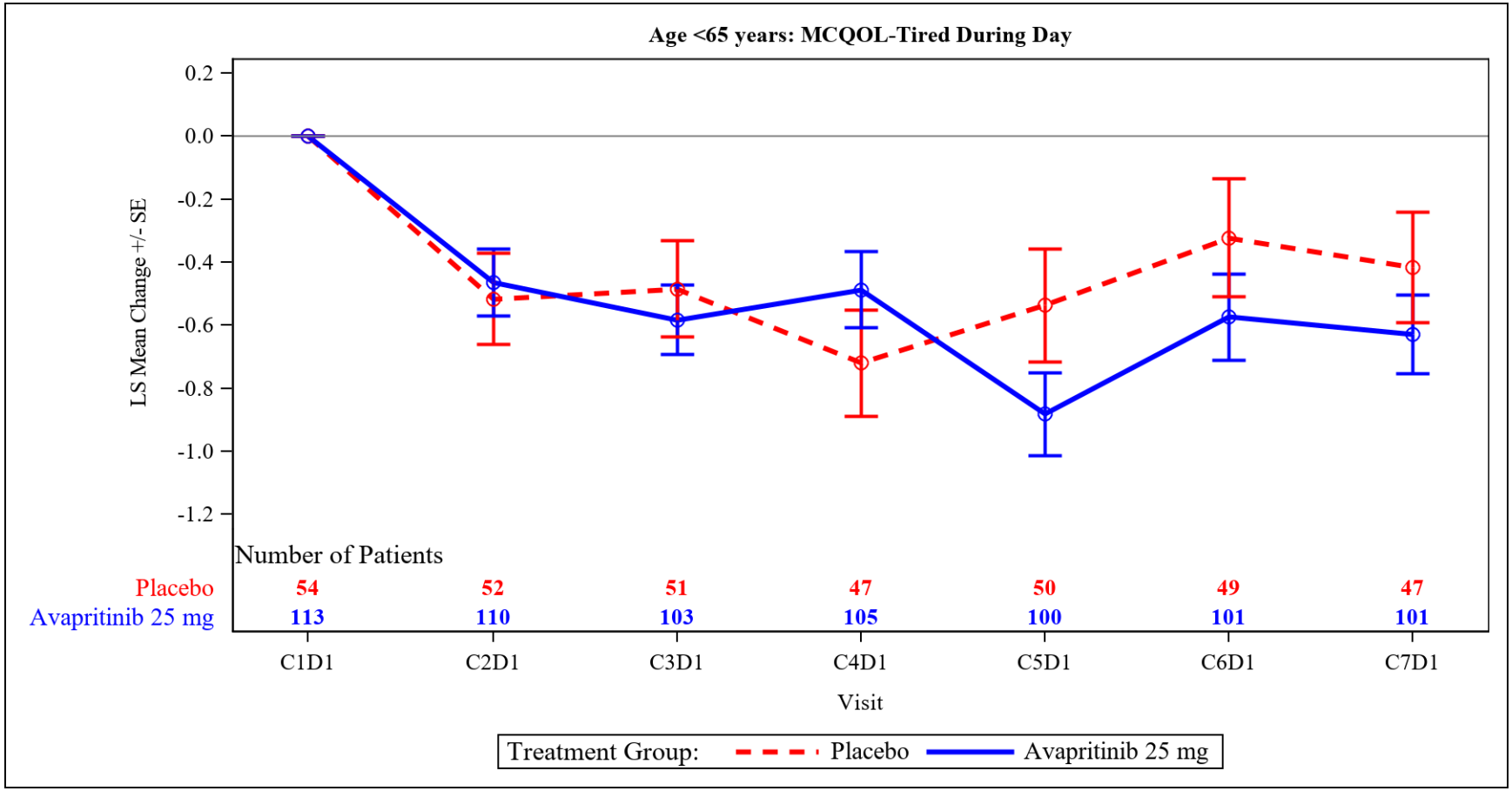

Figure 35.2.12.2.1a
LSMean Plot of Change from Baseline in Individual MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

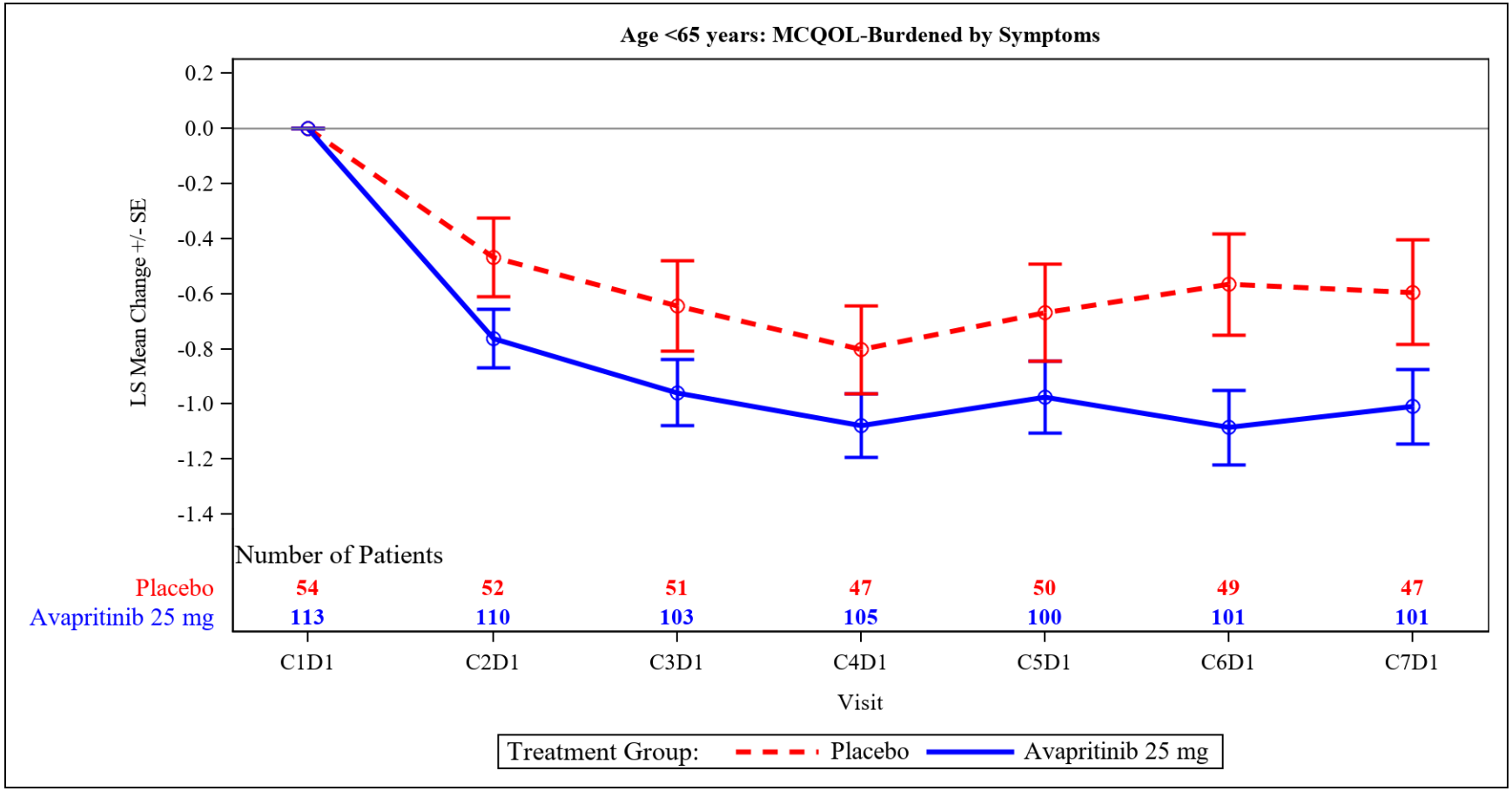

Figure 35.2.12.2.1a
LSMean Plot of Change from Baseline in Individual MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

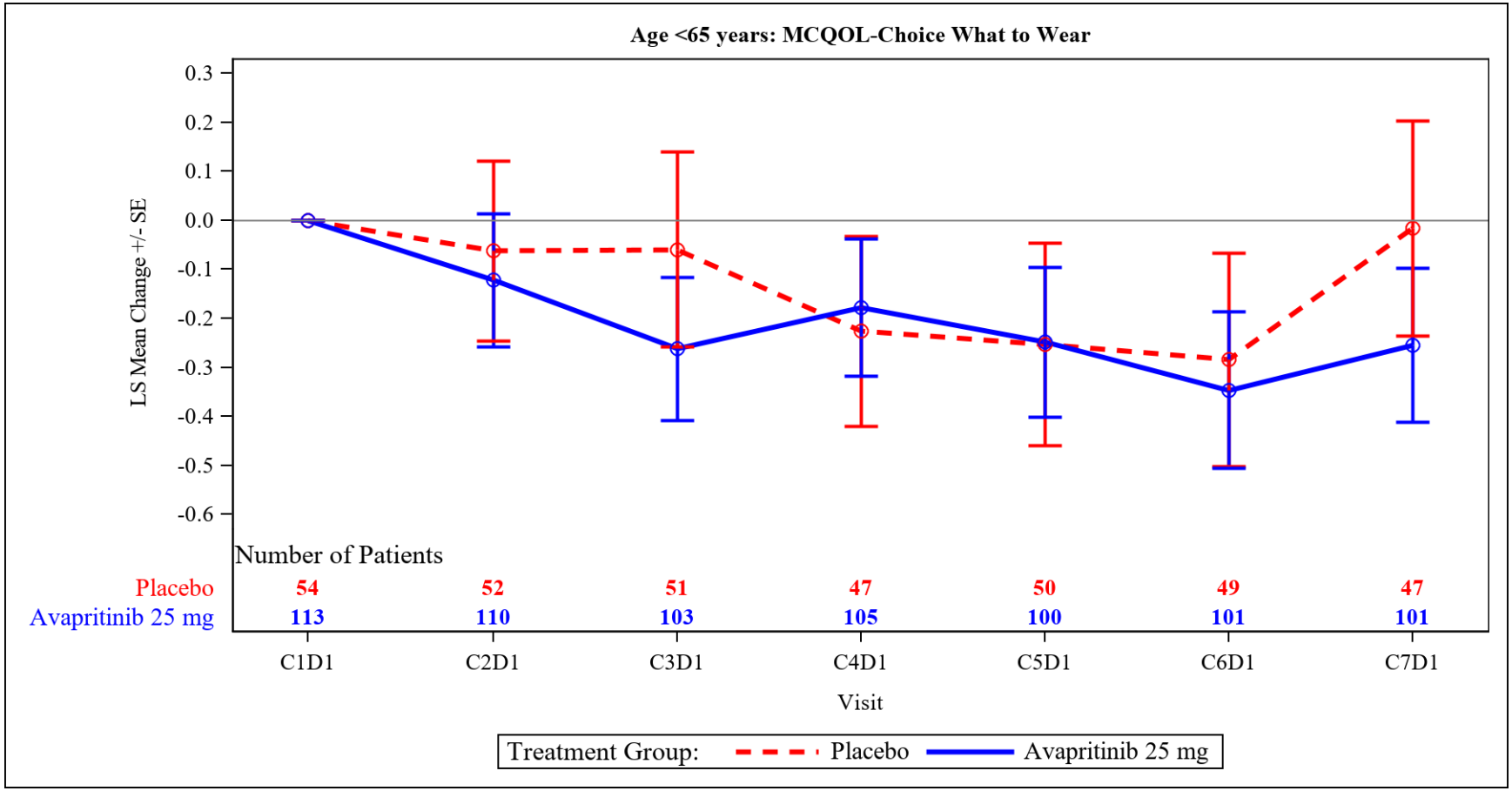

Figure 35.2.12.2.1a
LSMean Plot of Change from Baseline in Individual MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

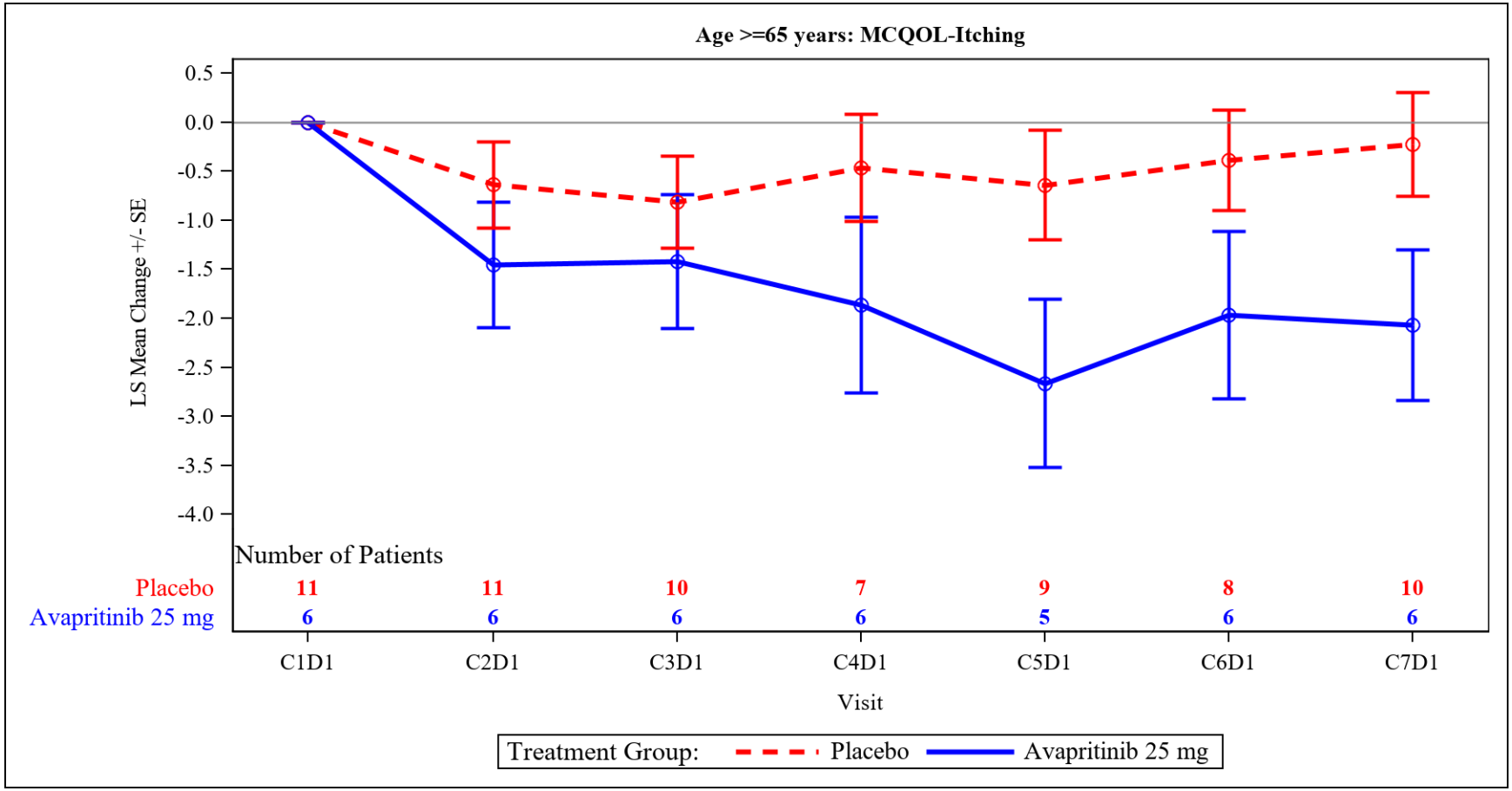

Figure 35.2.12.2.1a
LSMean Plot of Change from Baseline in Individual MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

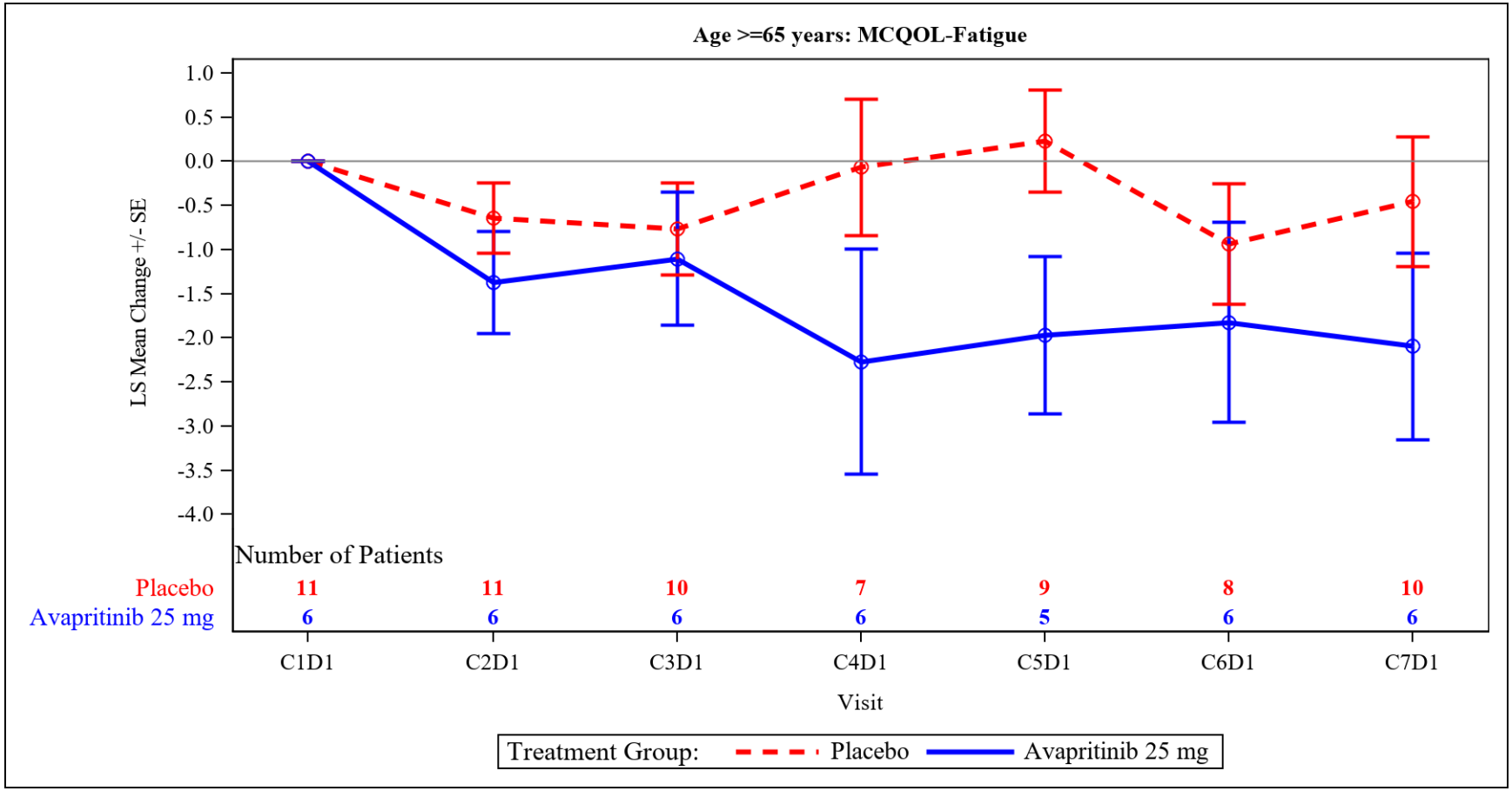

Figure 35.2.12.2.1a
LSMean Plot of Change from Baseline in Individual MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

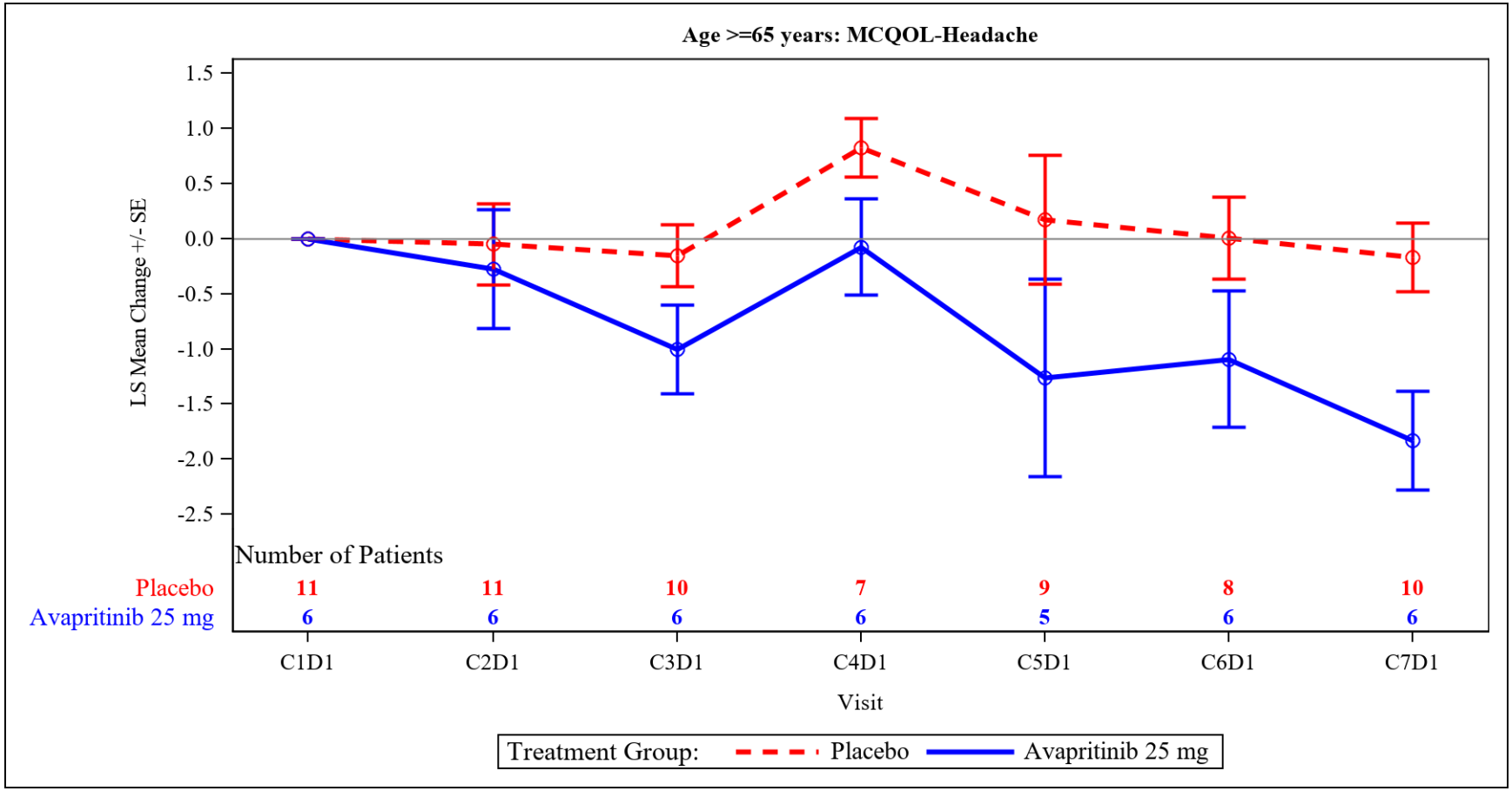

Figure 35.2.12.2.1a
LSMean Plot of Change from Baseline in Individual MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

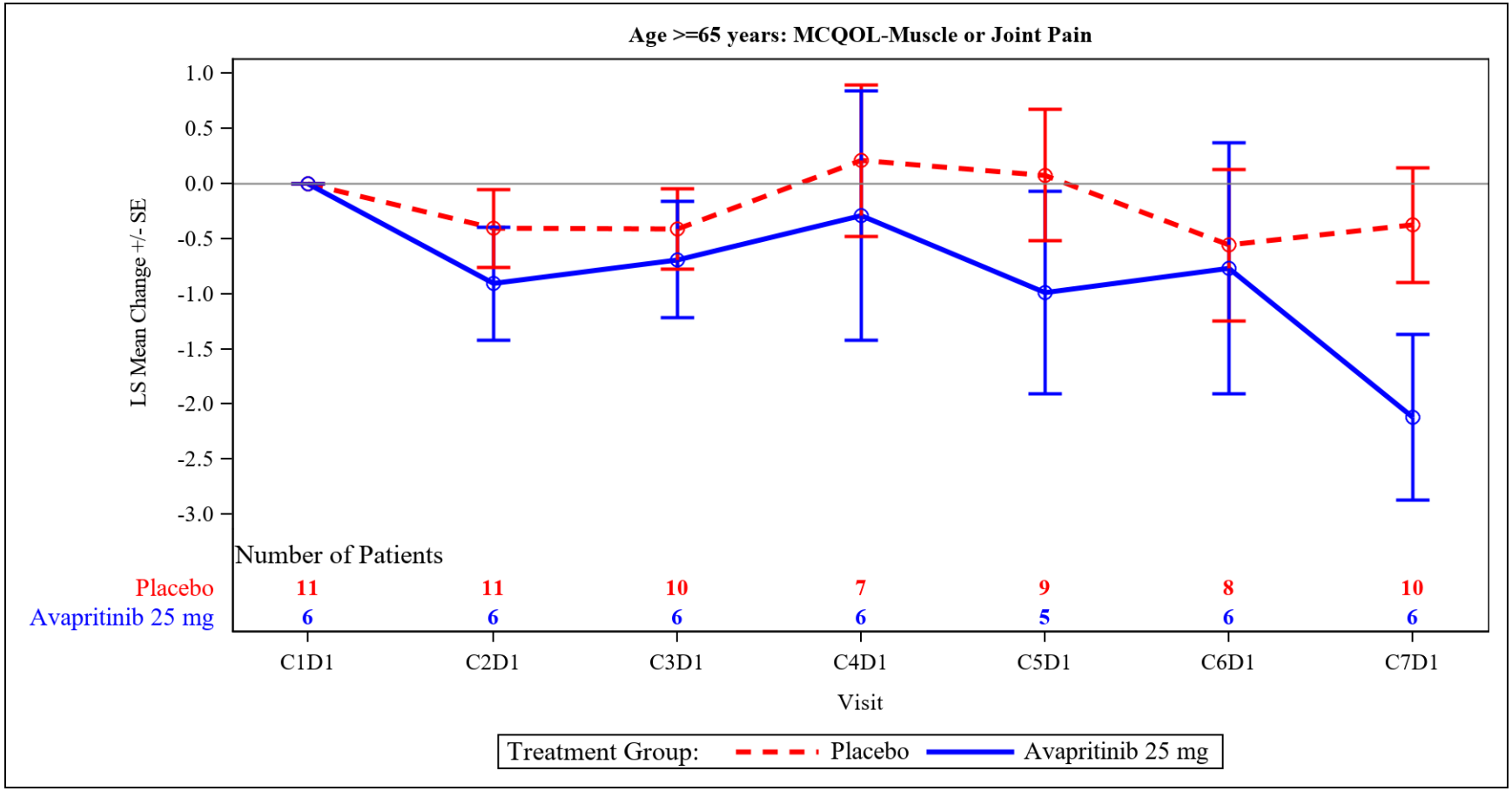

Figure 35.2.12.2.1a
LSMean Plot of Change from Baseline in Individual MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

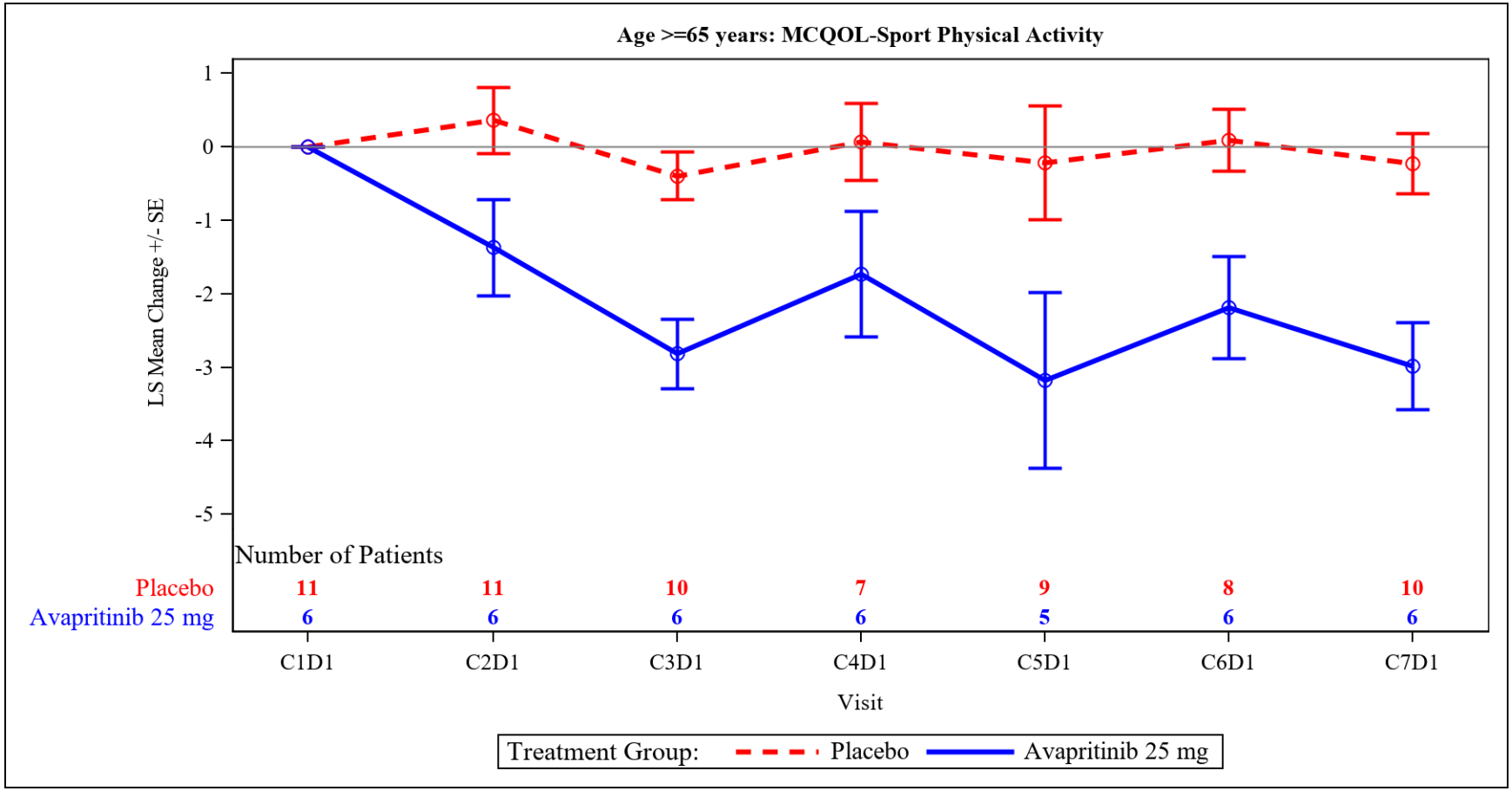

Figure 35.2.12.2.1a
LSMean Plot of Change from Baseline in Individual MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

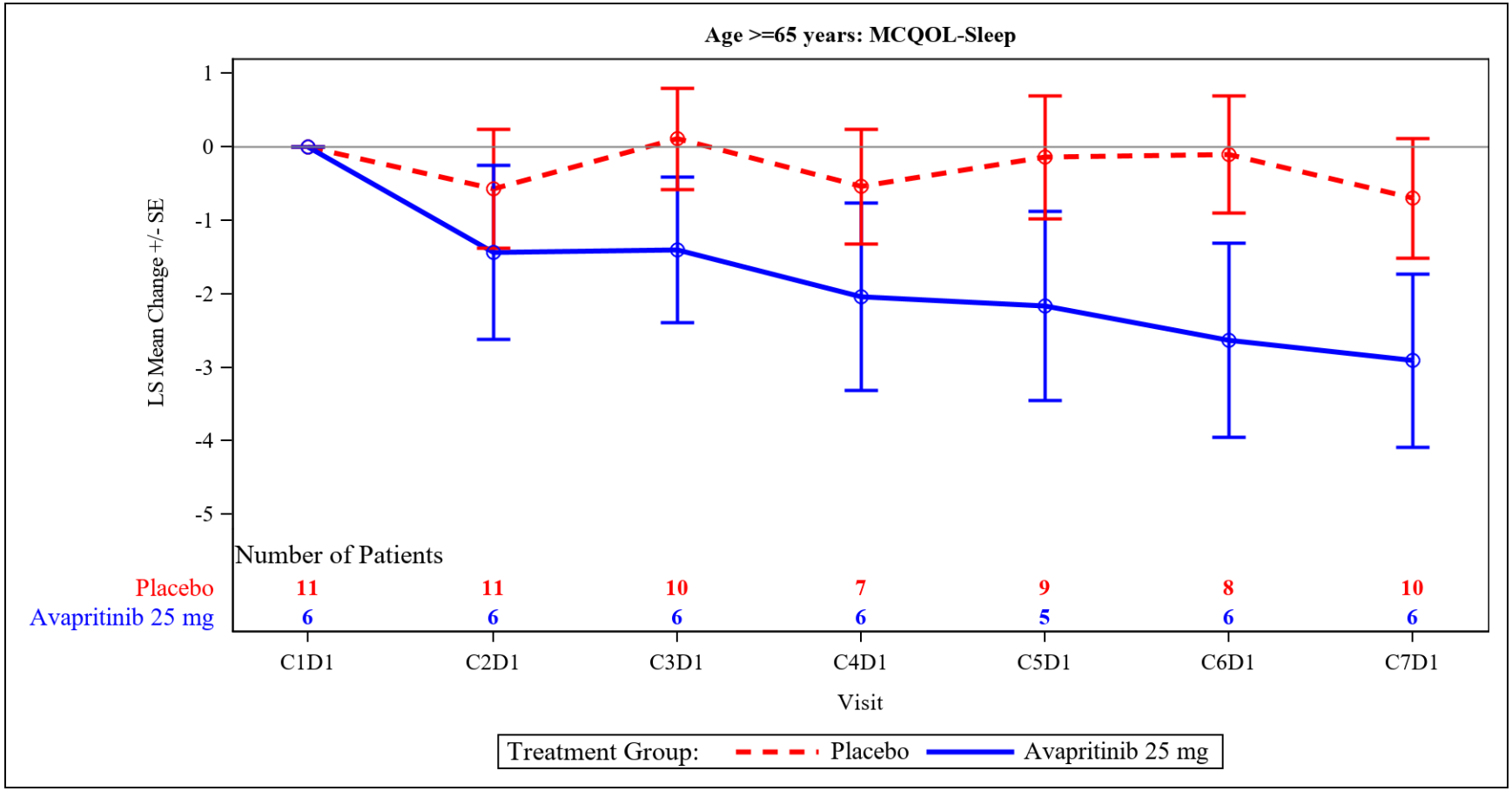

Figure 35.2.12.2.1a
LSMean Plot of Change from Baseline in Individual MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

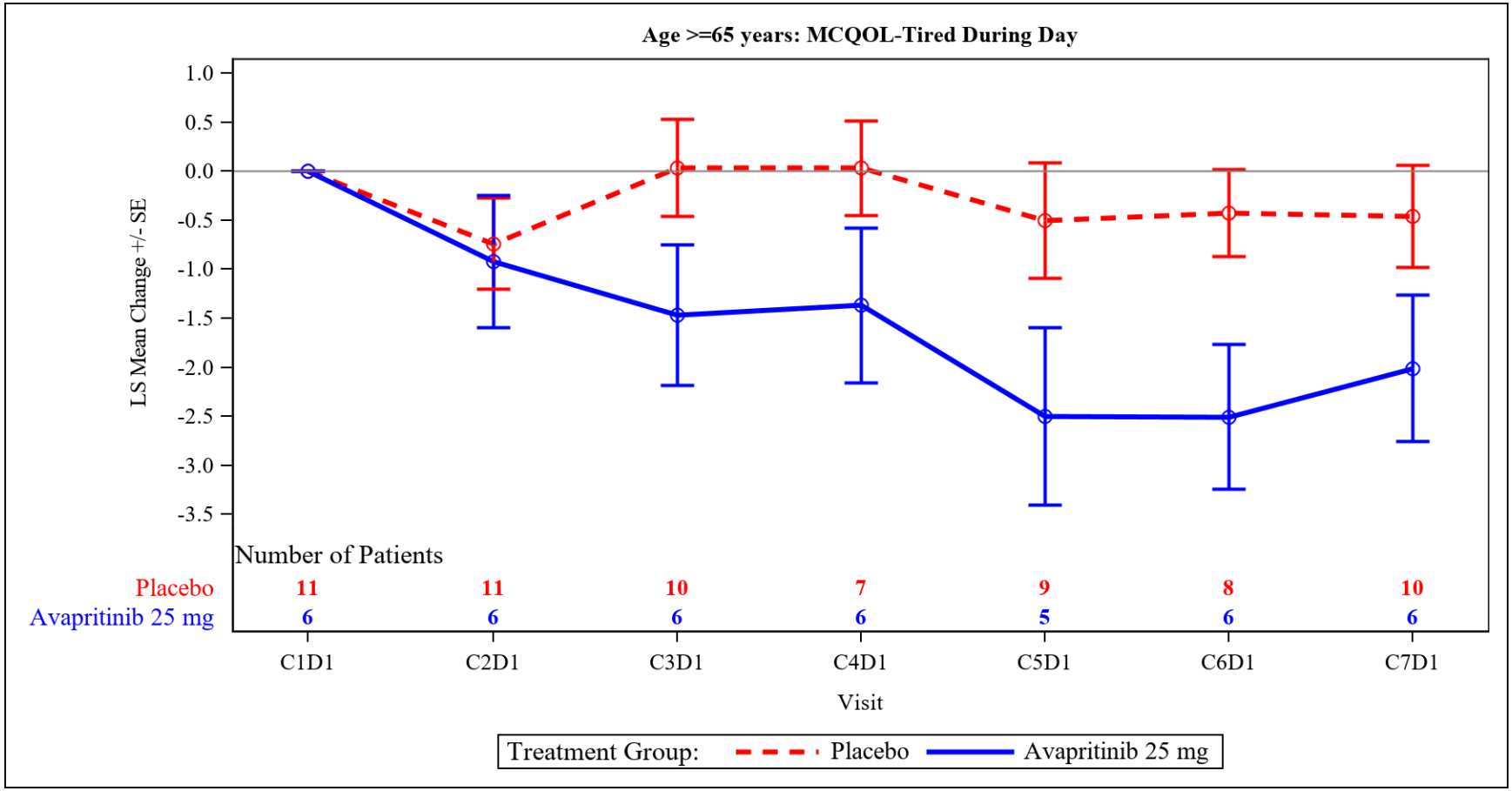

Figure 35.2.12.2.1a
LSMean Plot of Change from Baseline in Individual MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

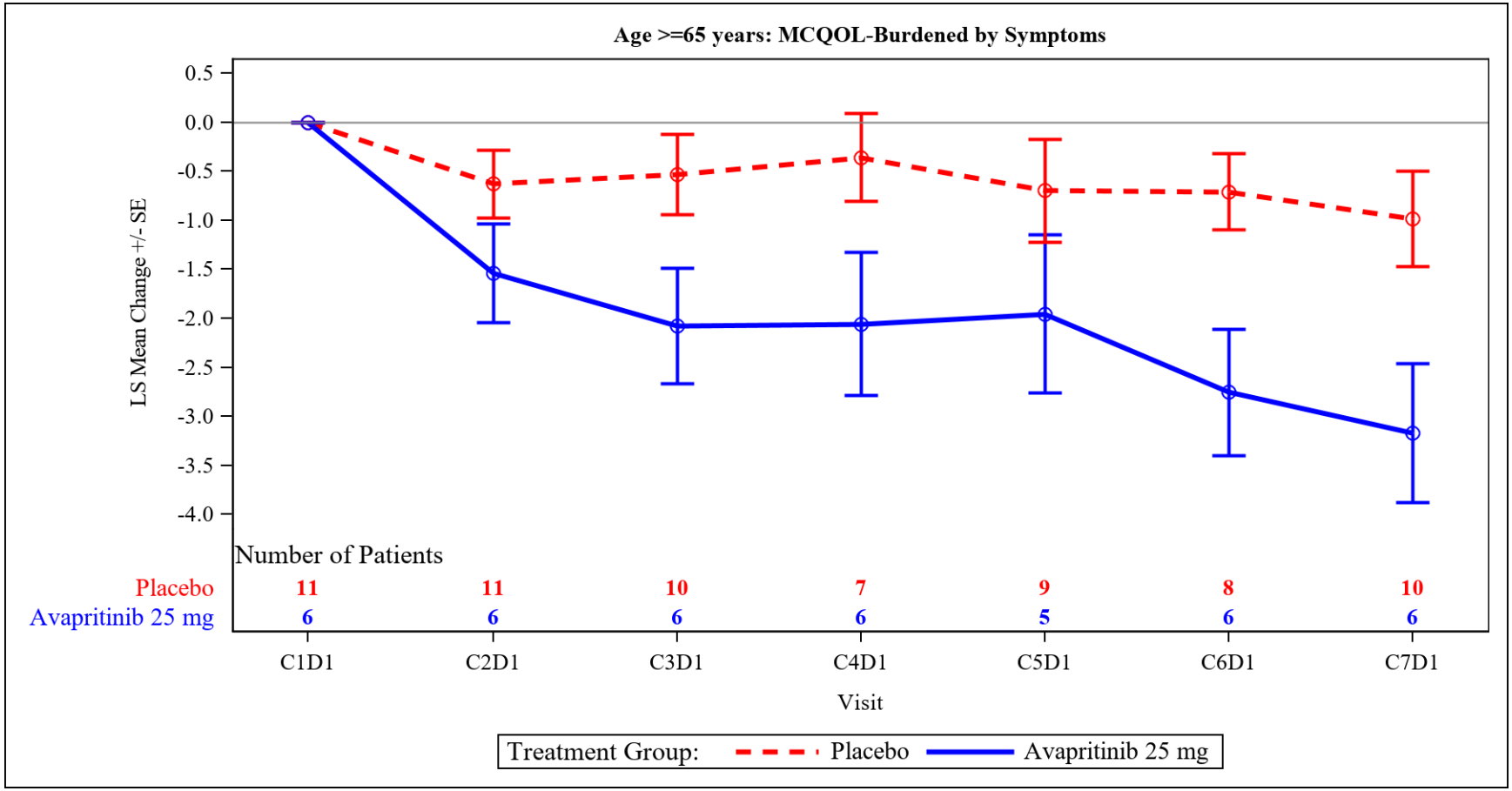

Figure 35.2.12.2.1a
LSMean Plot of Change from Baseline in Individual MC-QoL by Age Group
Per-Protocol Population, Part 2 (Part 2 Baseline)

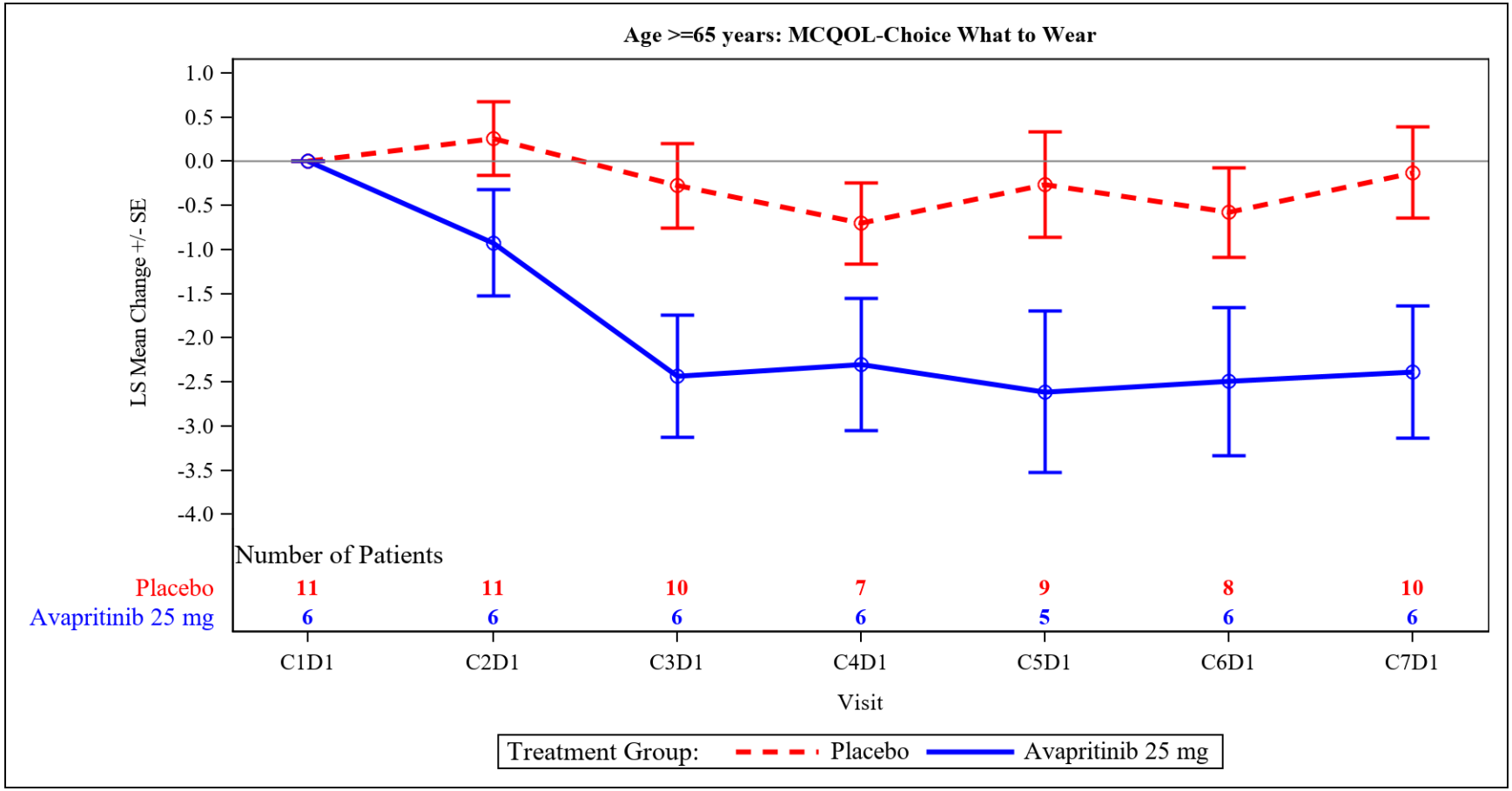

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Figure 35.2.2.3.2.2a
LSMean Plot of Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

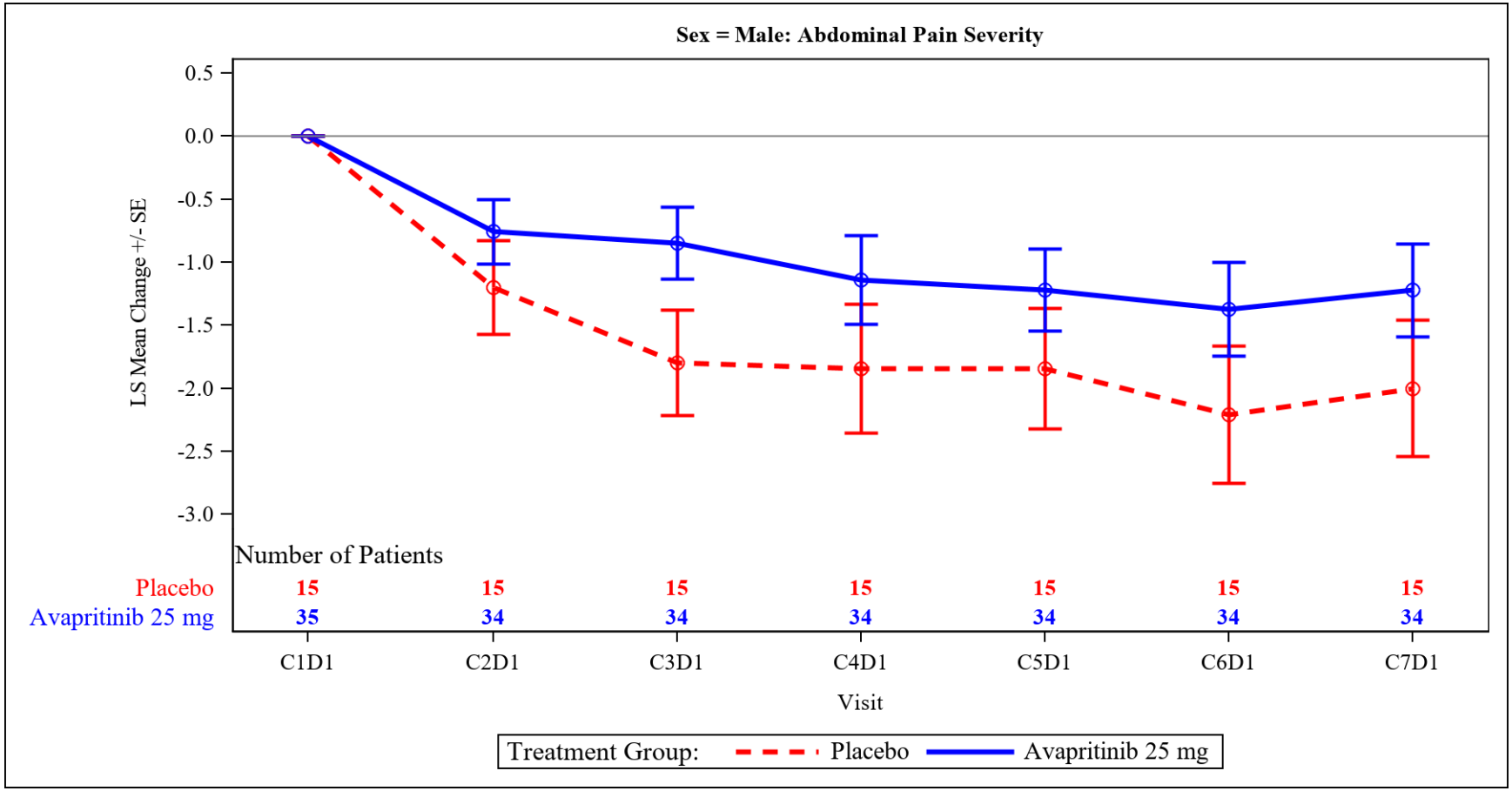

Figure 35.2.2.3.2.2a
LSMean Plot of Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

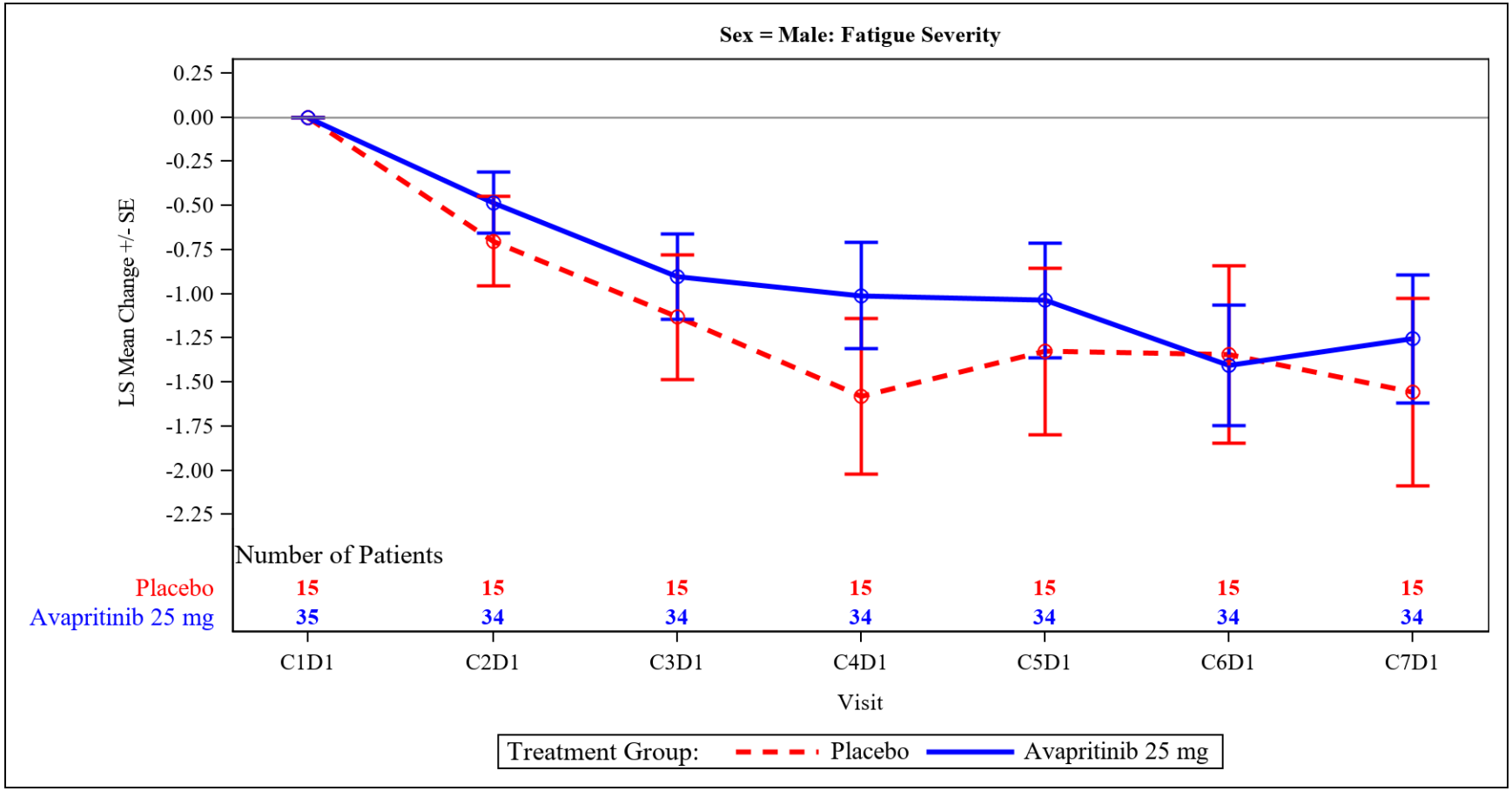

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Figure 35.2.2.3.2.2a
LSMean Plot of Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

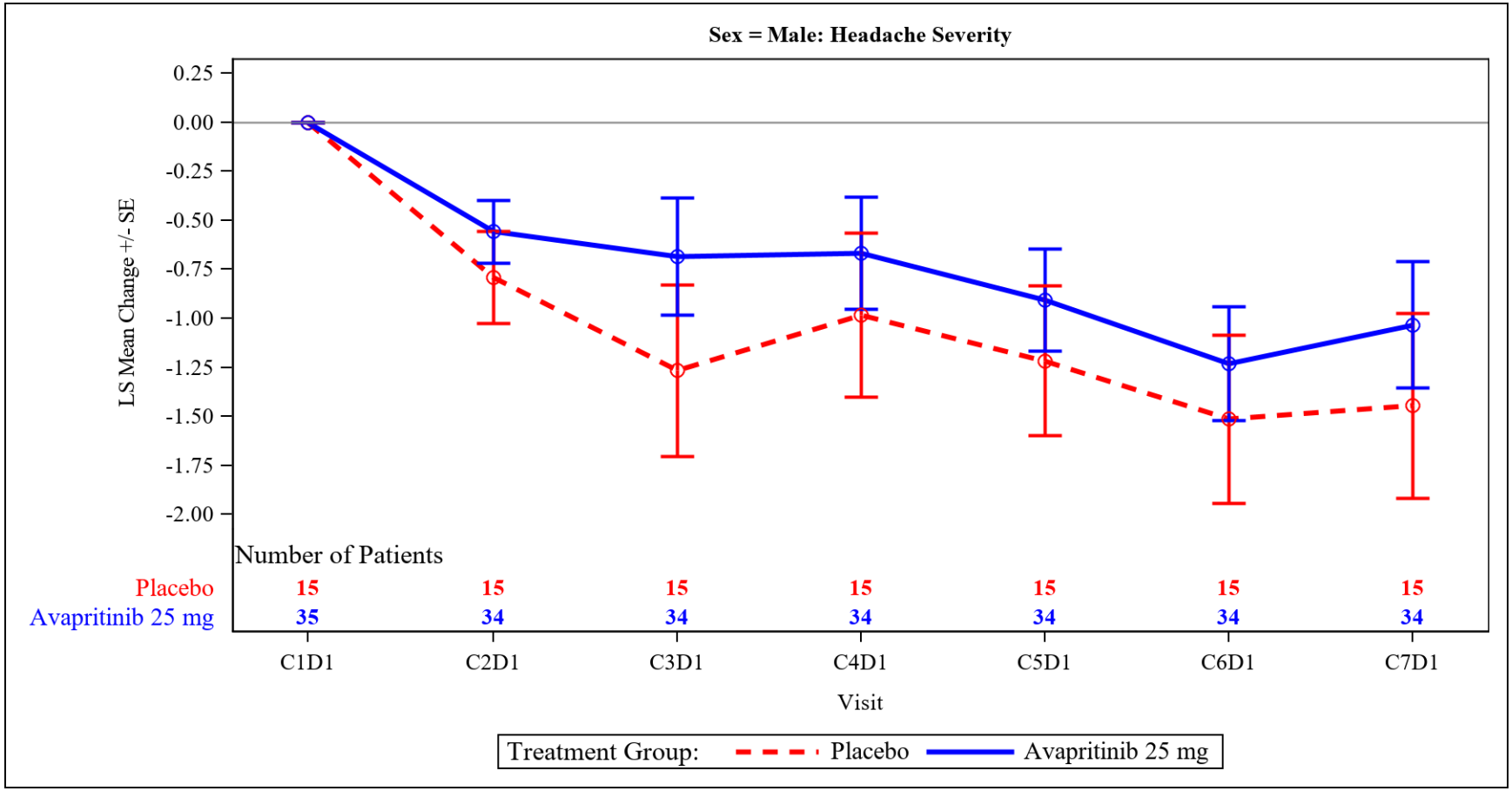

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Figure 35.2.2.3.2.2a
LSMean Plot of Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

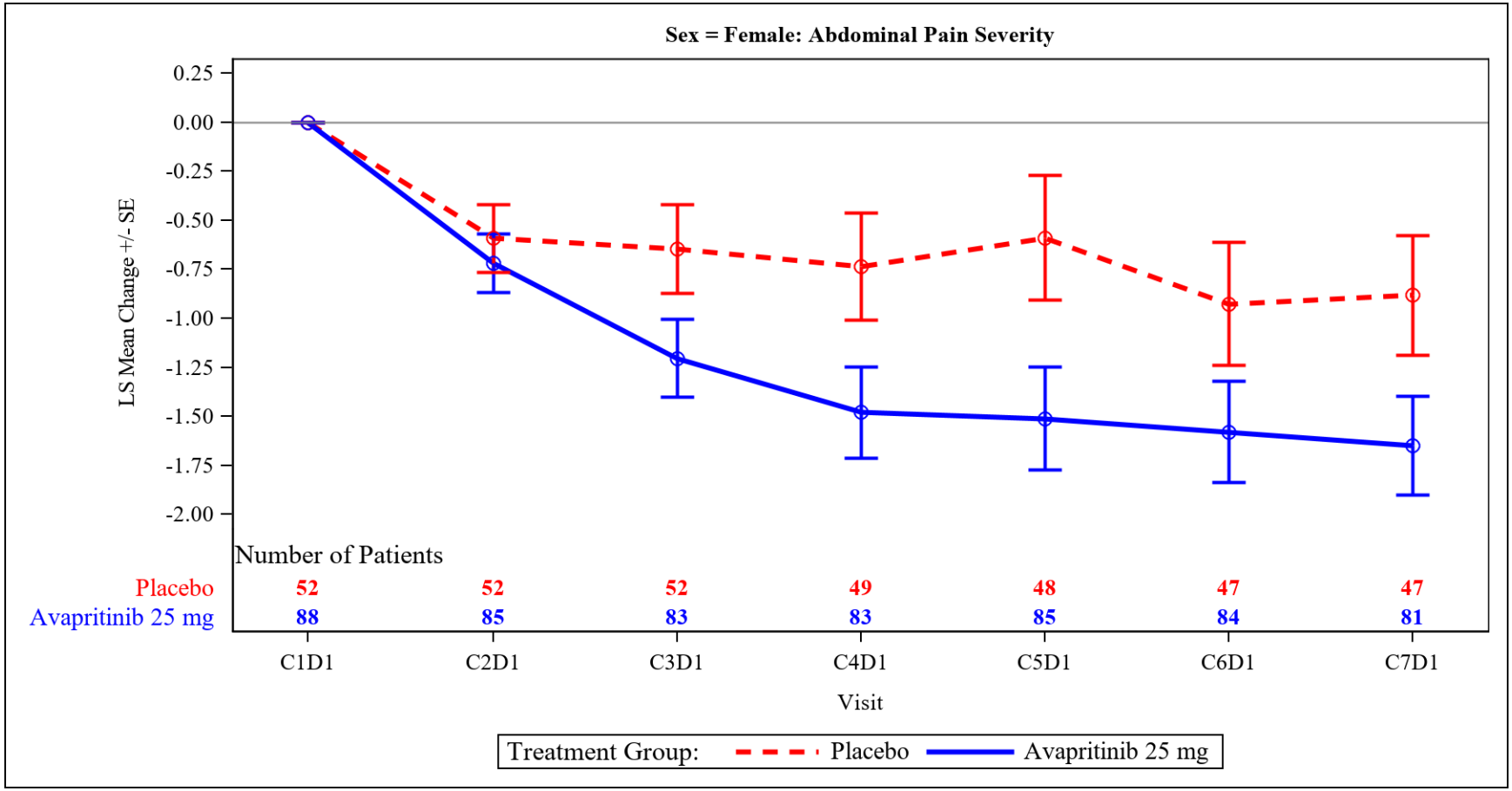

Figure 35.2.2.3.2.2a
LSMean Plot of Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

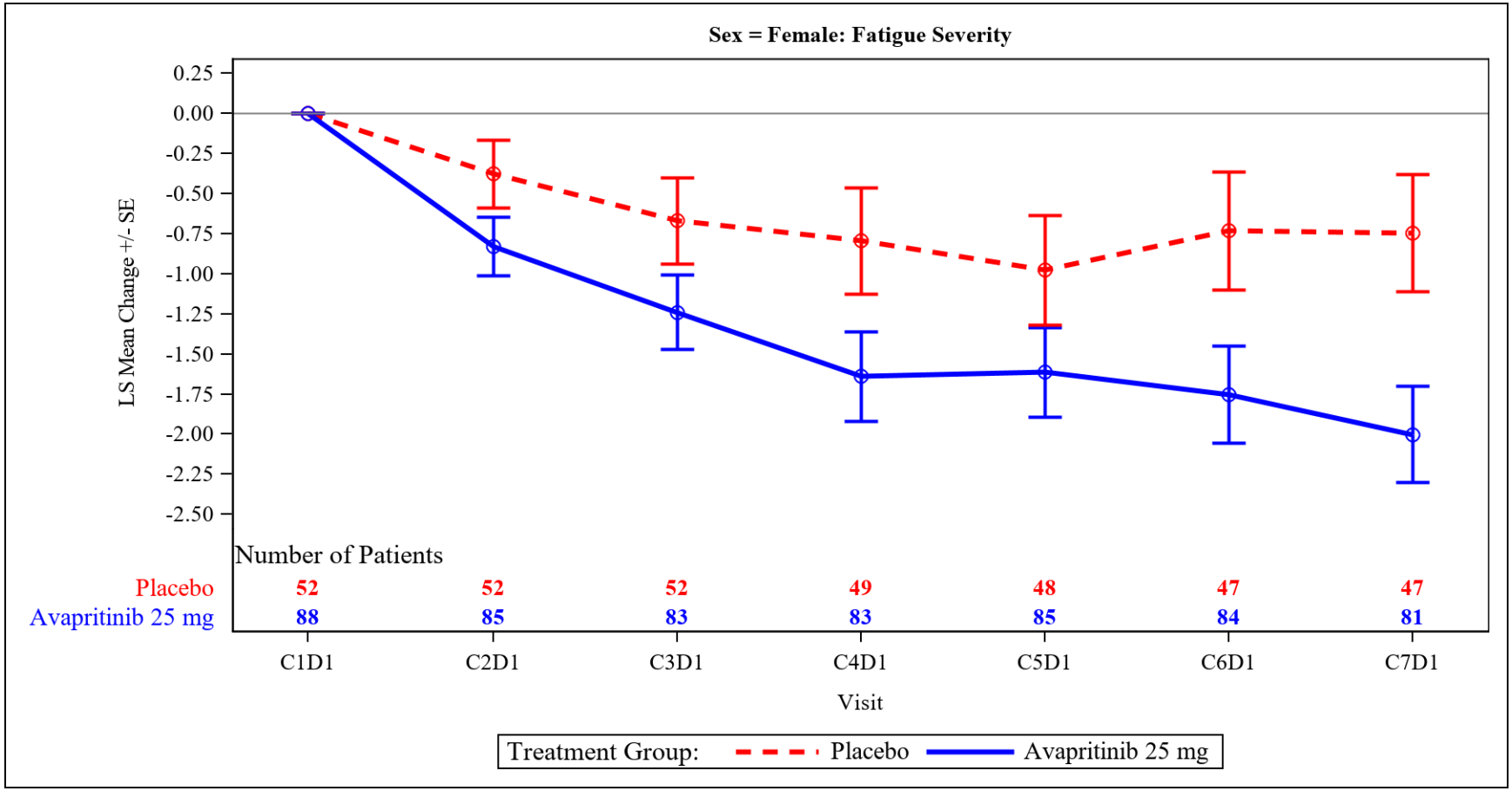

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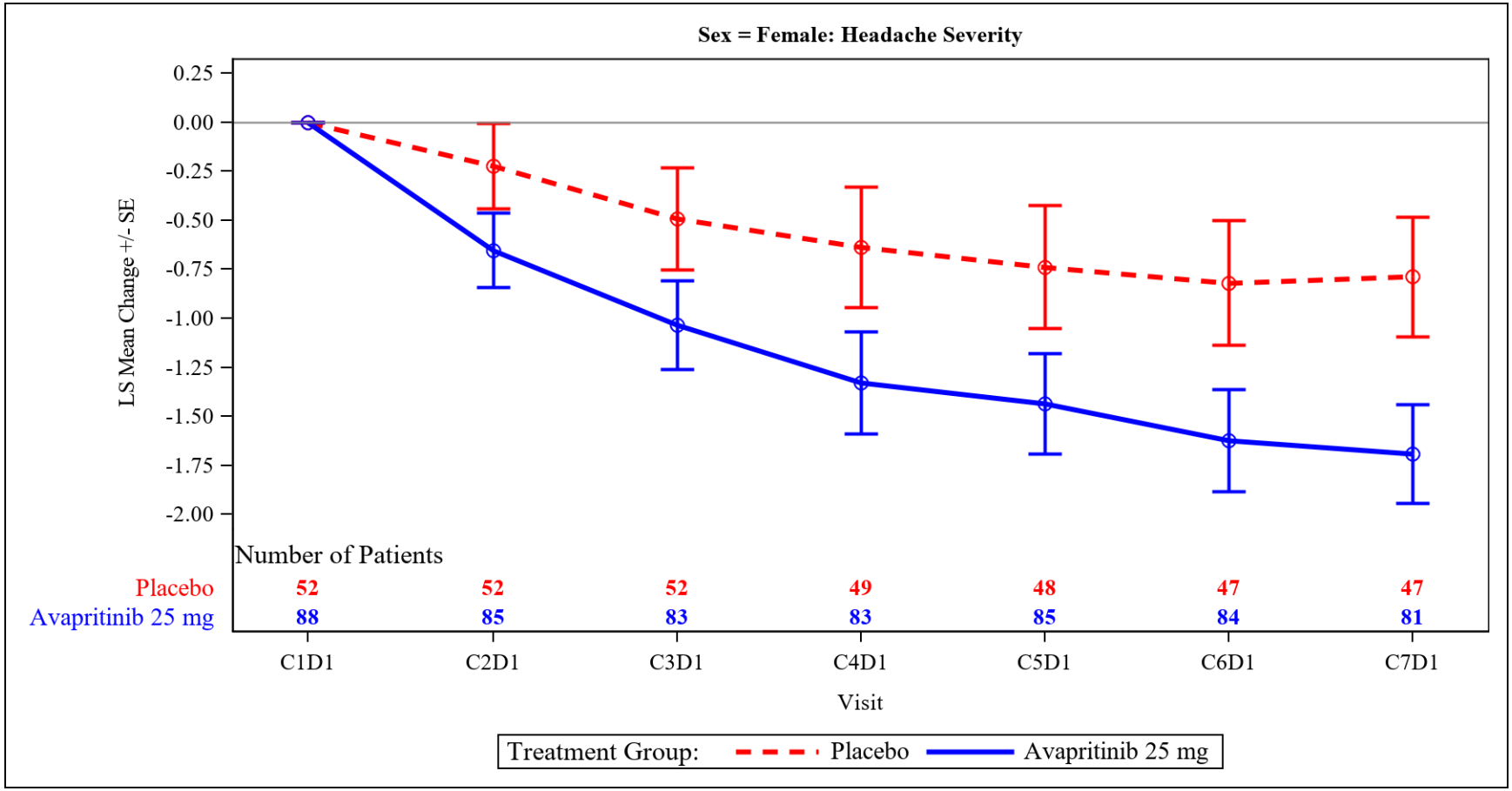
Figure 35.2.2.3.2.2a
LSMean Plot of Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)



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CSR Germany

Figure 35.2.11.4.2.2a
LSMean Plot of Mastocytosis in Skin by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)

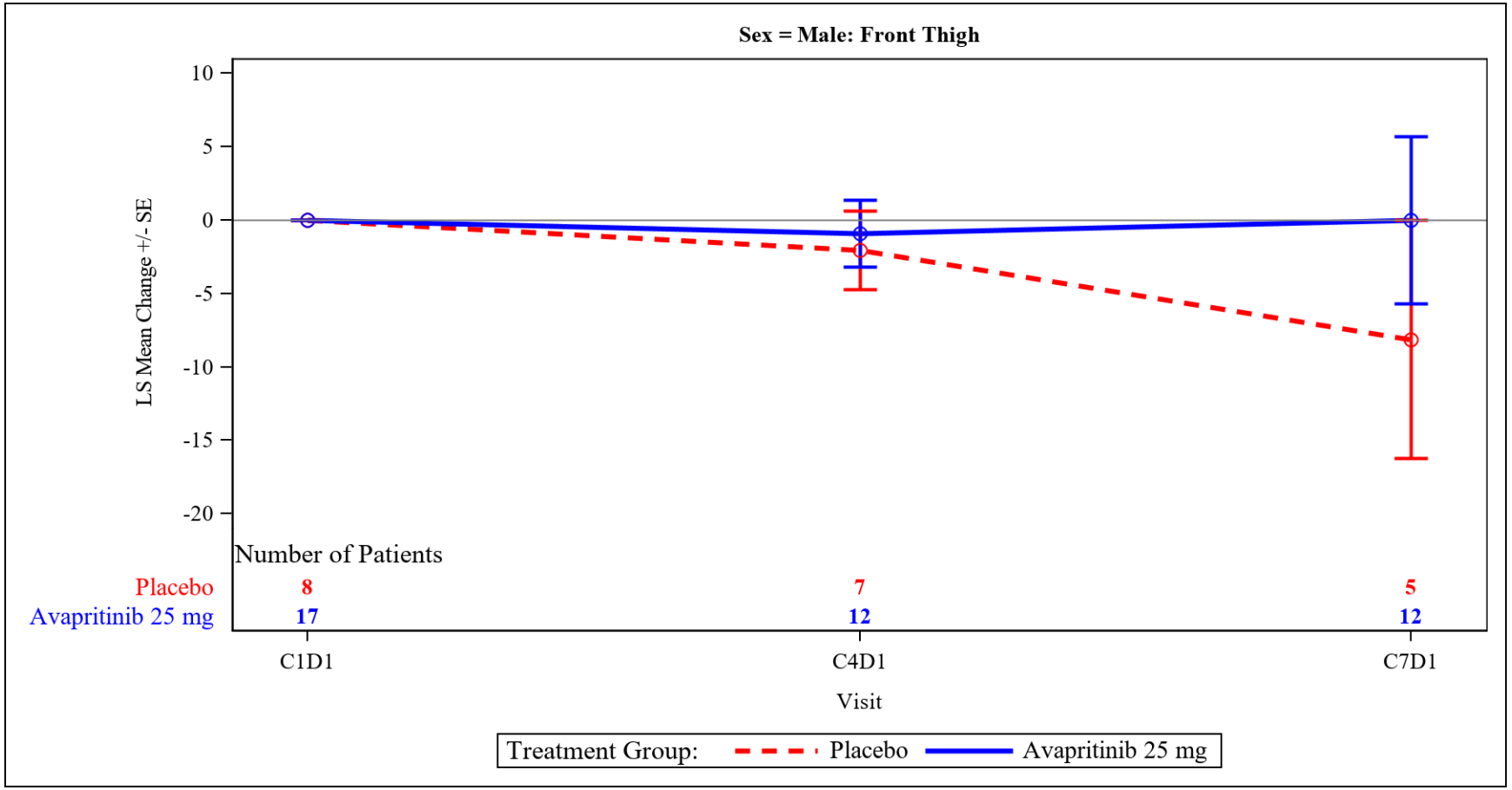

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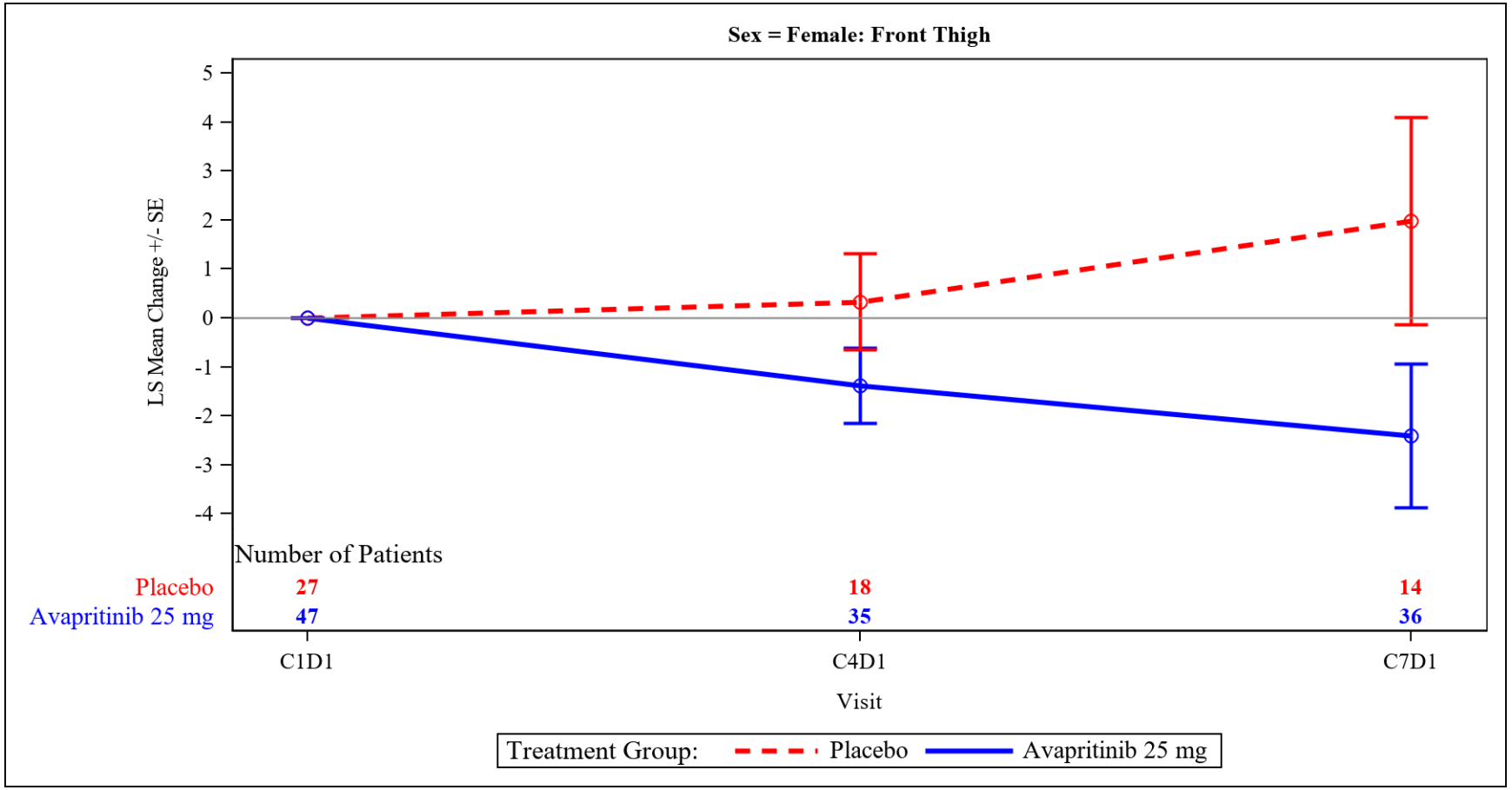
Figure 35.2.11.4.2.2a
LSMean Plot of Mastocytosis in Skin by Sex
Per-Protocol Population, Part 2 (Part 2 Baseline)



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CSR Germany

Figure 35.2.12.2.3a
LSMean Plot of Change from Baseline in Individual MC-QoL by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

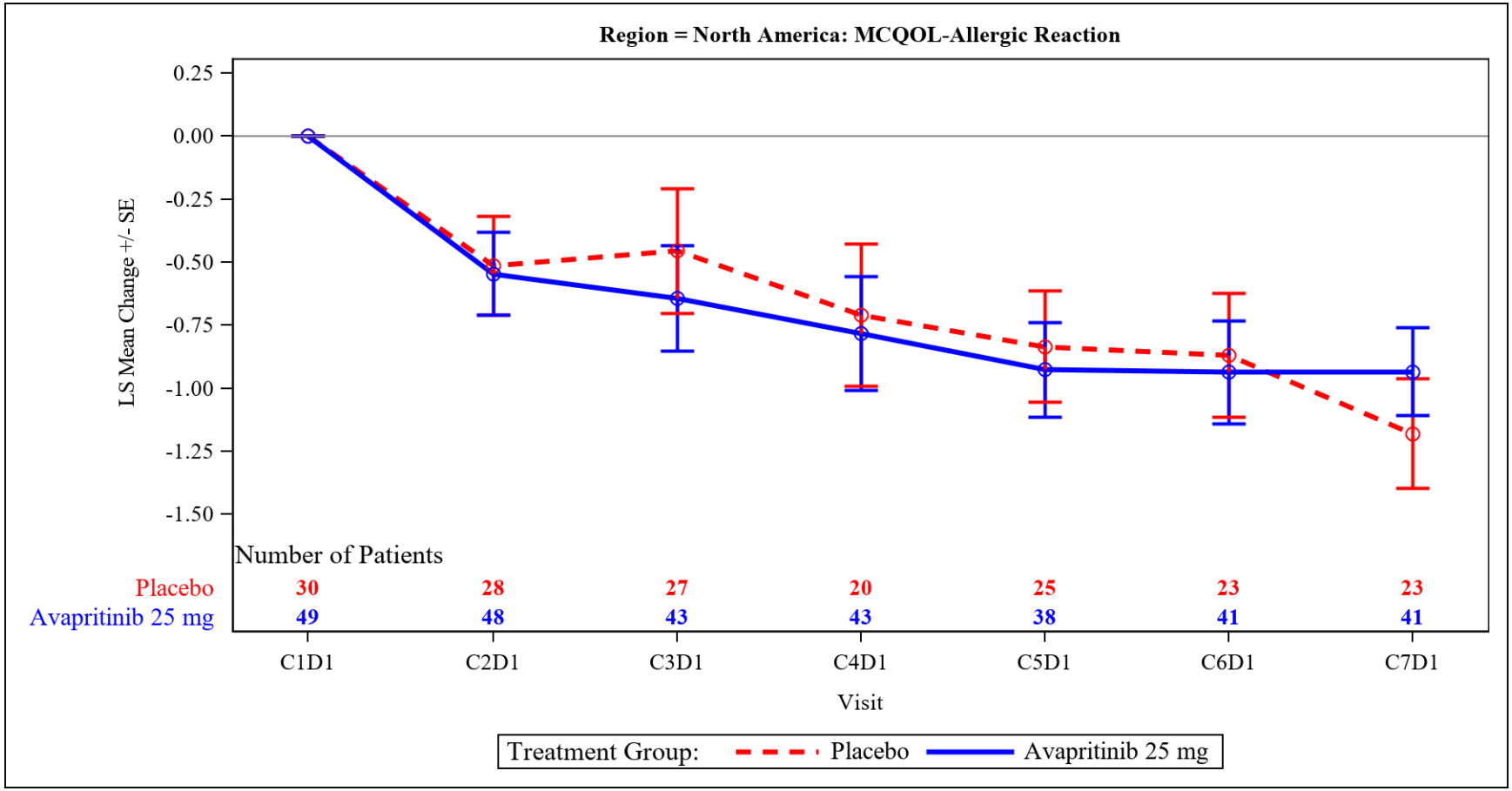

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Figure 35.2.12.2.3a
LSMean Plot of Change from Baseline in Individual MC-QoL by Region
Per-Protocol Population, Part 2 (Part 2 Baseline)

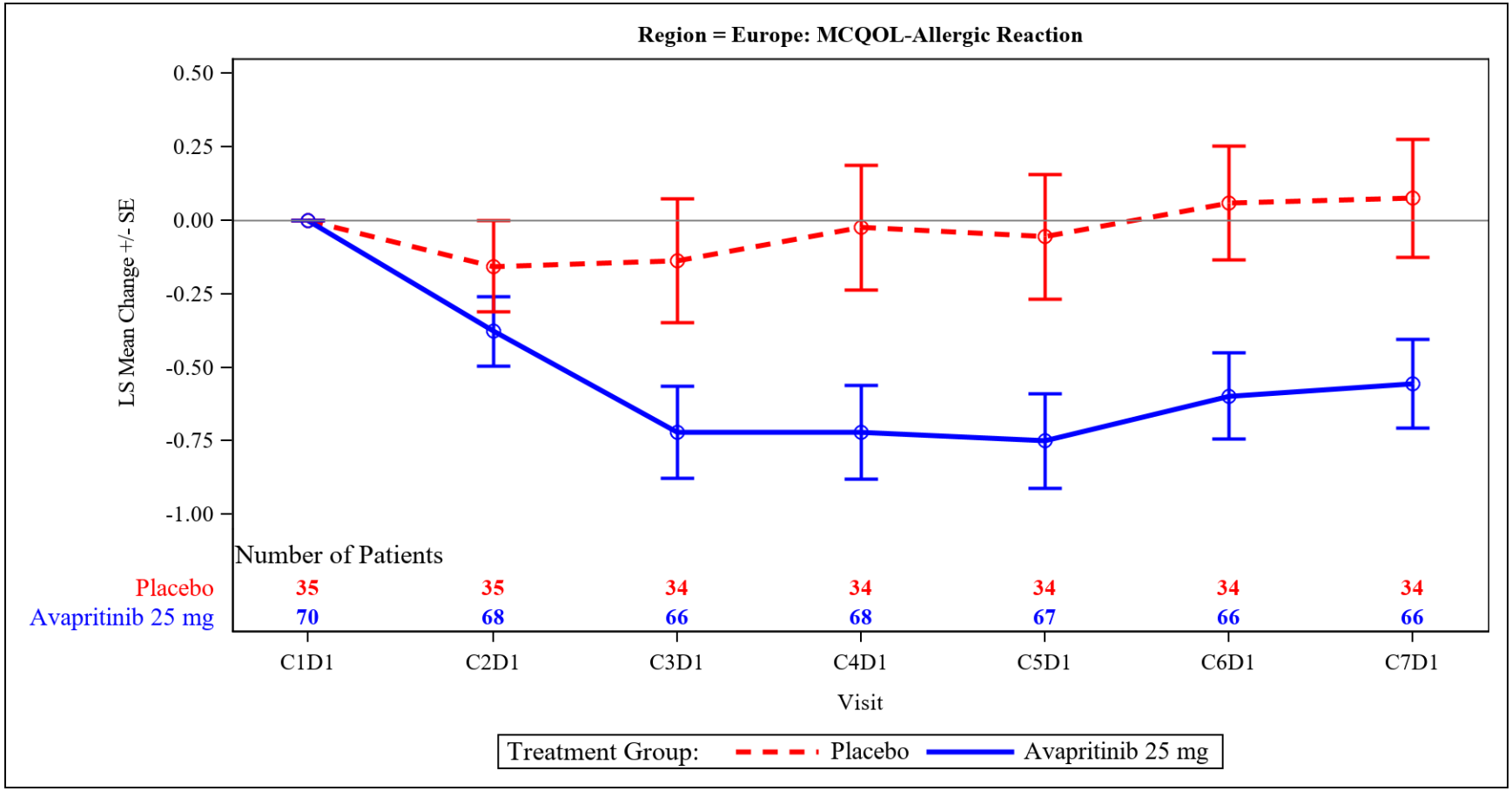

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Figure 35.2.1.2.2.6a
LSMean Plot of Change from Baseline in TSS of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

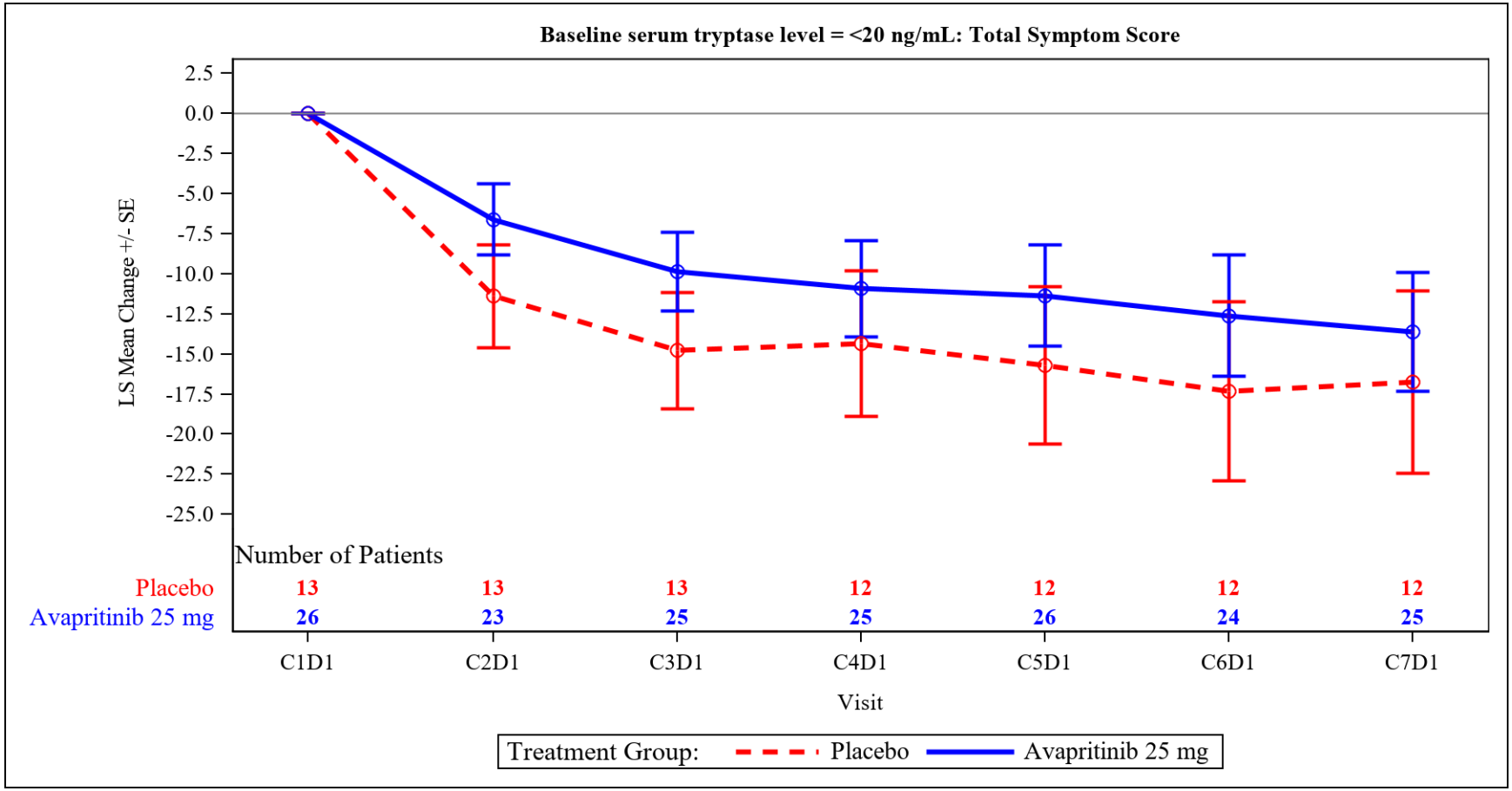

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Figure 35.2.1.2.2.6a
LSMean Plot of Change from Baseline in TSS of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

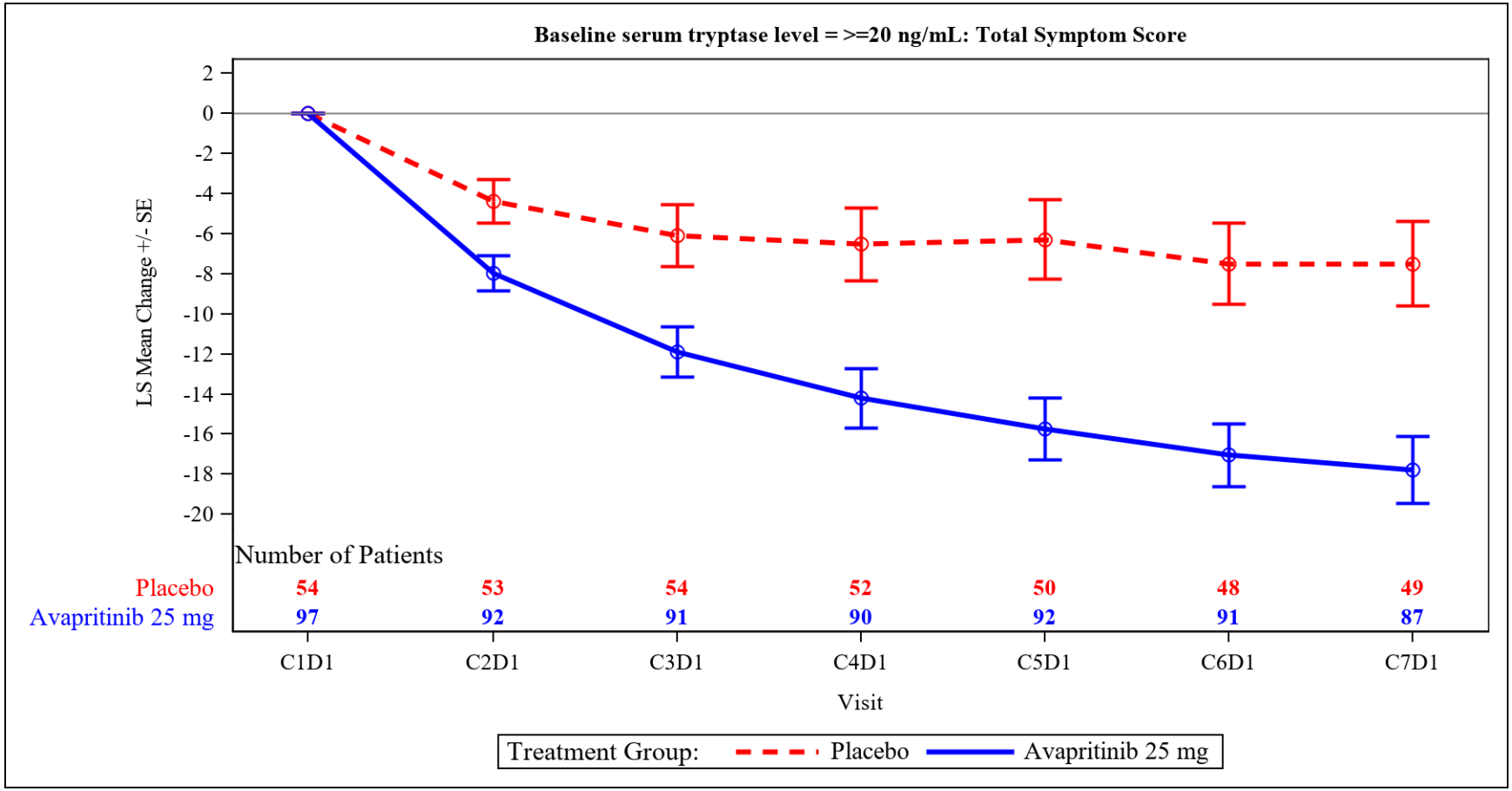

Figure 35.2.2.2.2.6a
LSMean Plot of Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline Serum Tryptase Level Per-Protocol Population, Part 2 (Part 2 Baseline)

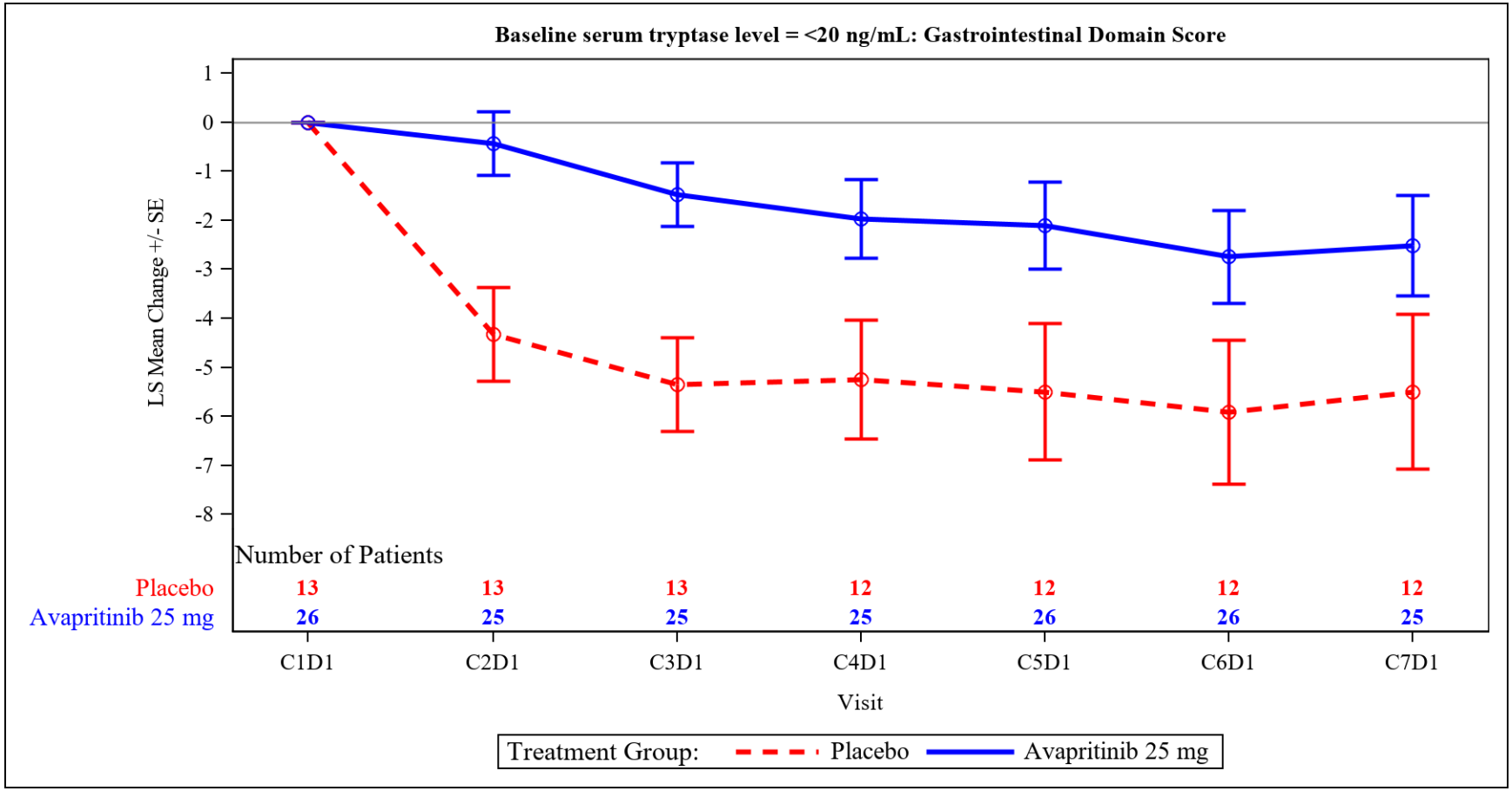

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Figure 35.2.2.2.2.6a
LSMean Plot of Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline Serum Tryptase Level Per-Protocol Population, Part 2 (Part 2 Baseline)

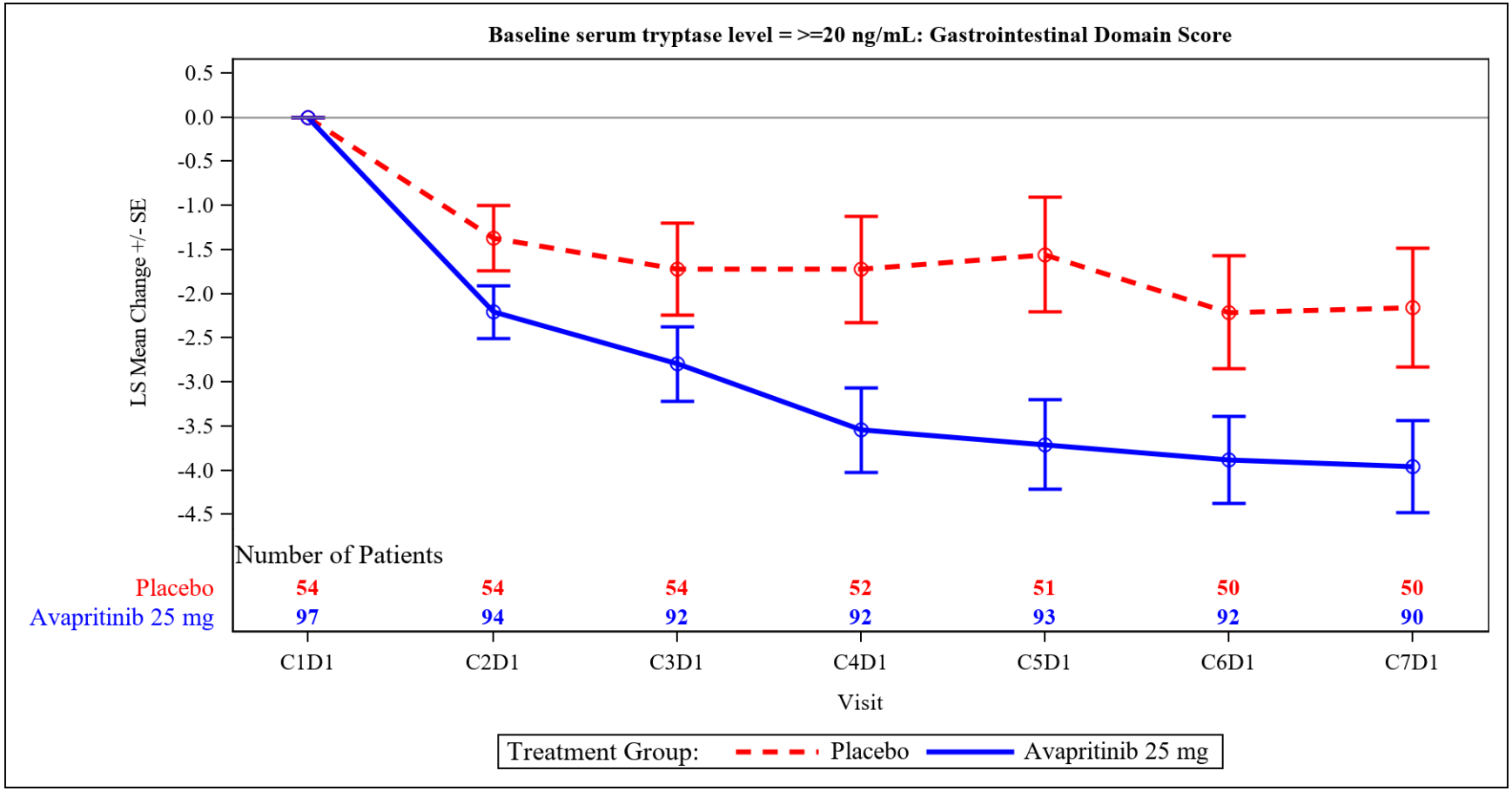

Figure 35.2.2.3.2.6a
LSMean Plot of Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

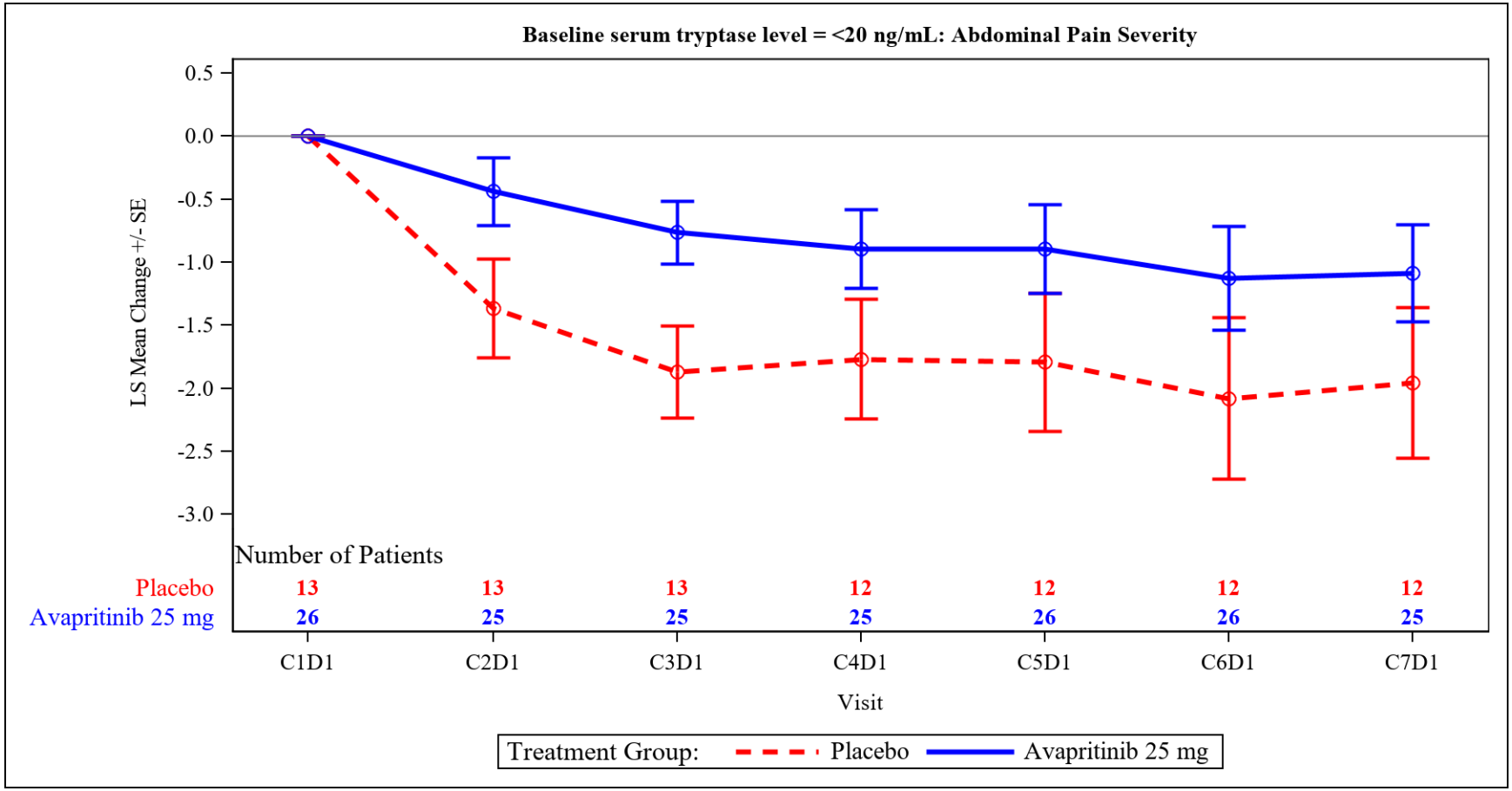

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Figure 35.2.2.3.2.6a
LSMean Plot of Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

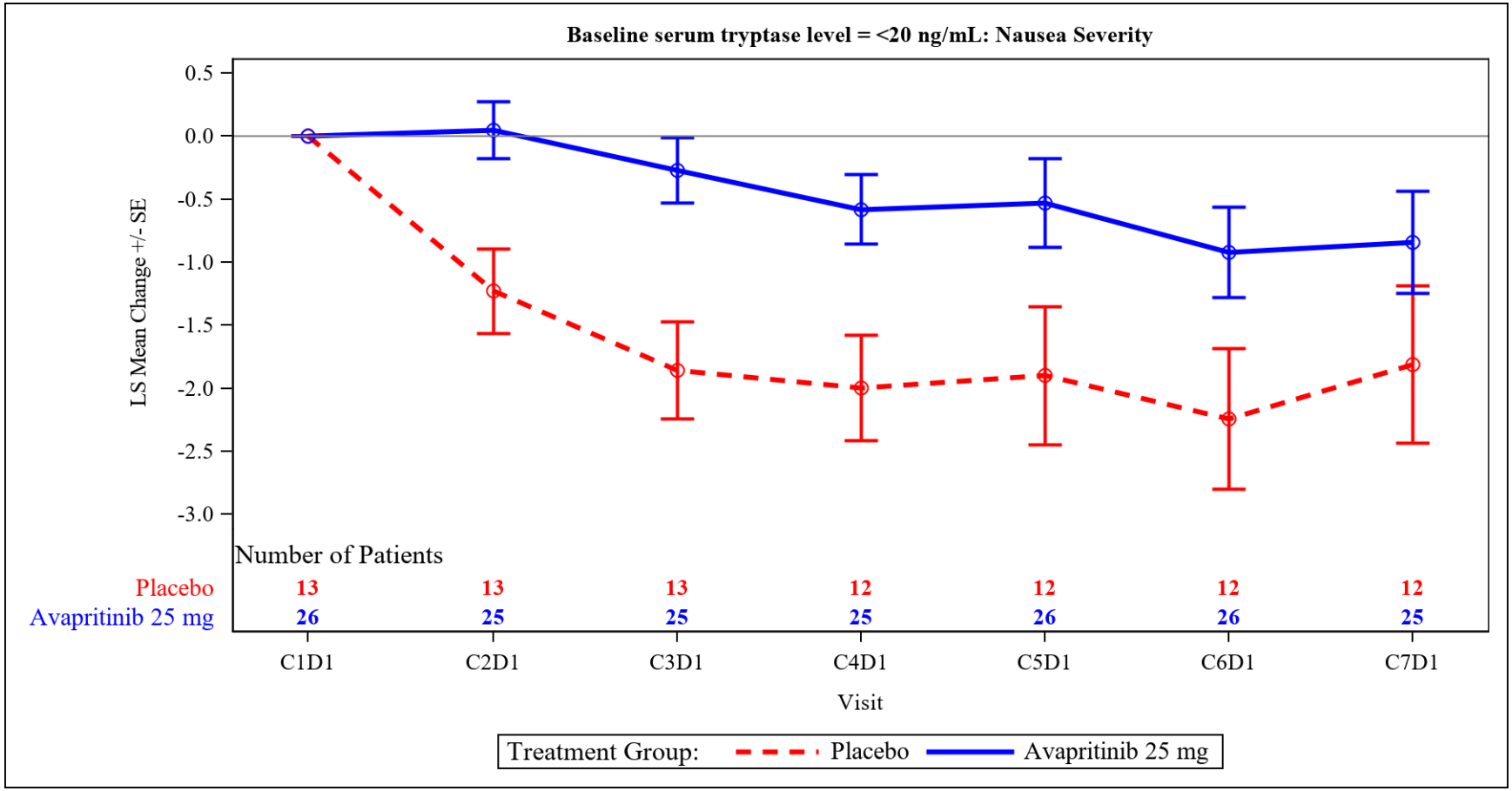

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Figure 35.2.2.3.2.6a
LSMean Plot of Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

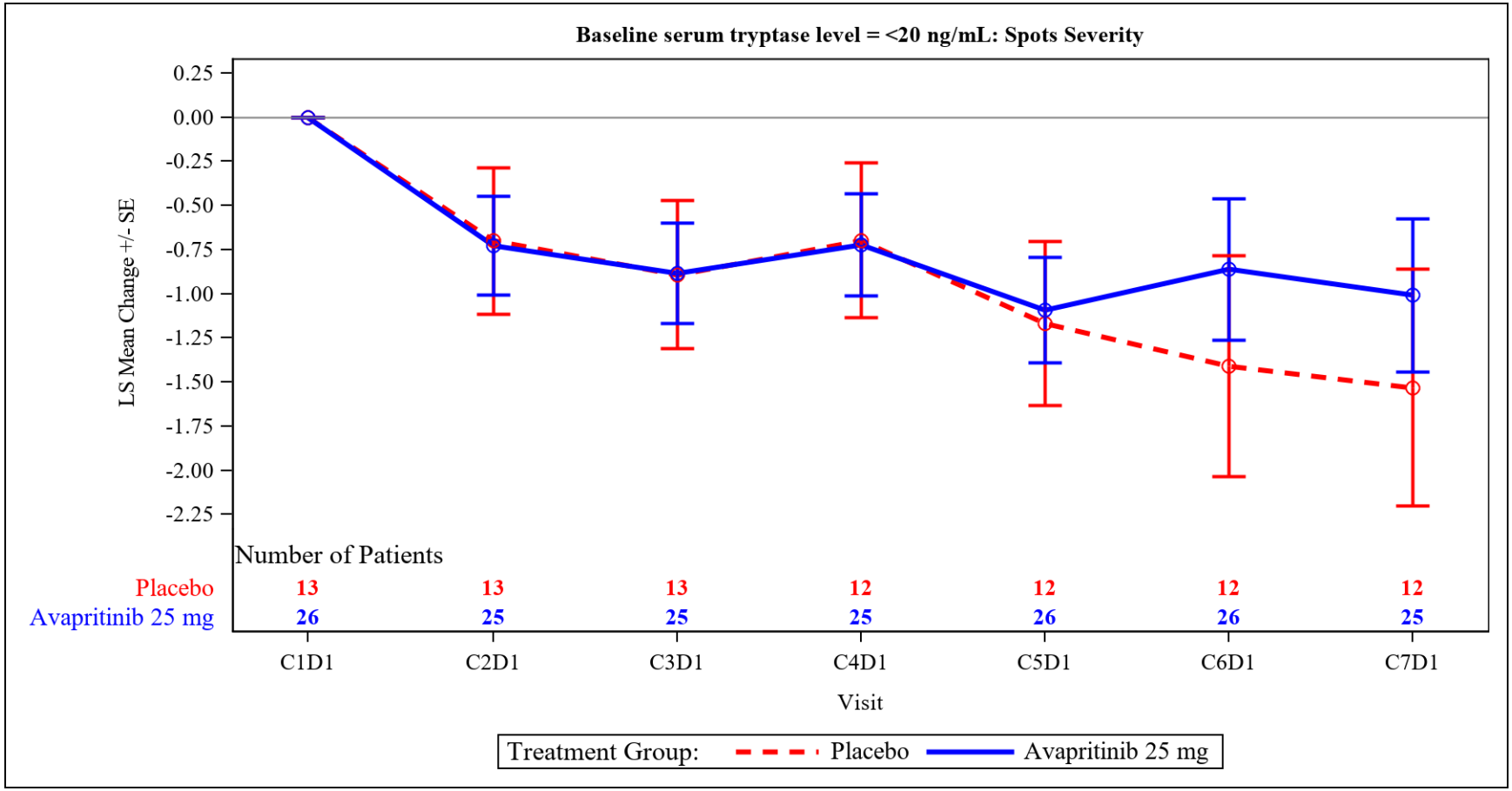

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Figure 35.2.2.3.2.6a
LSMean Plot of Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

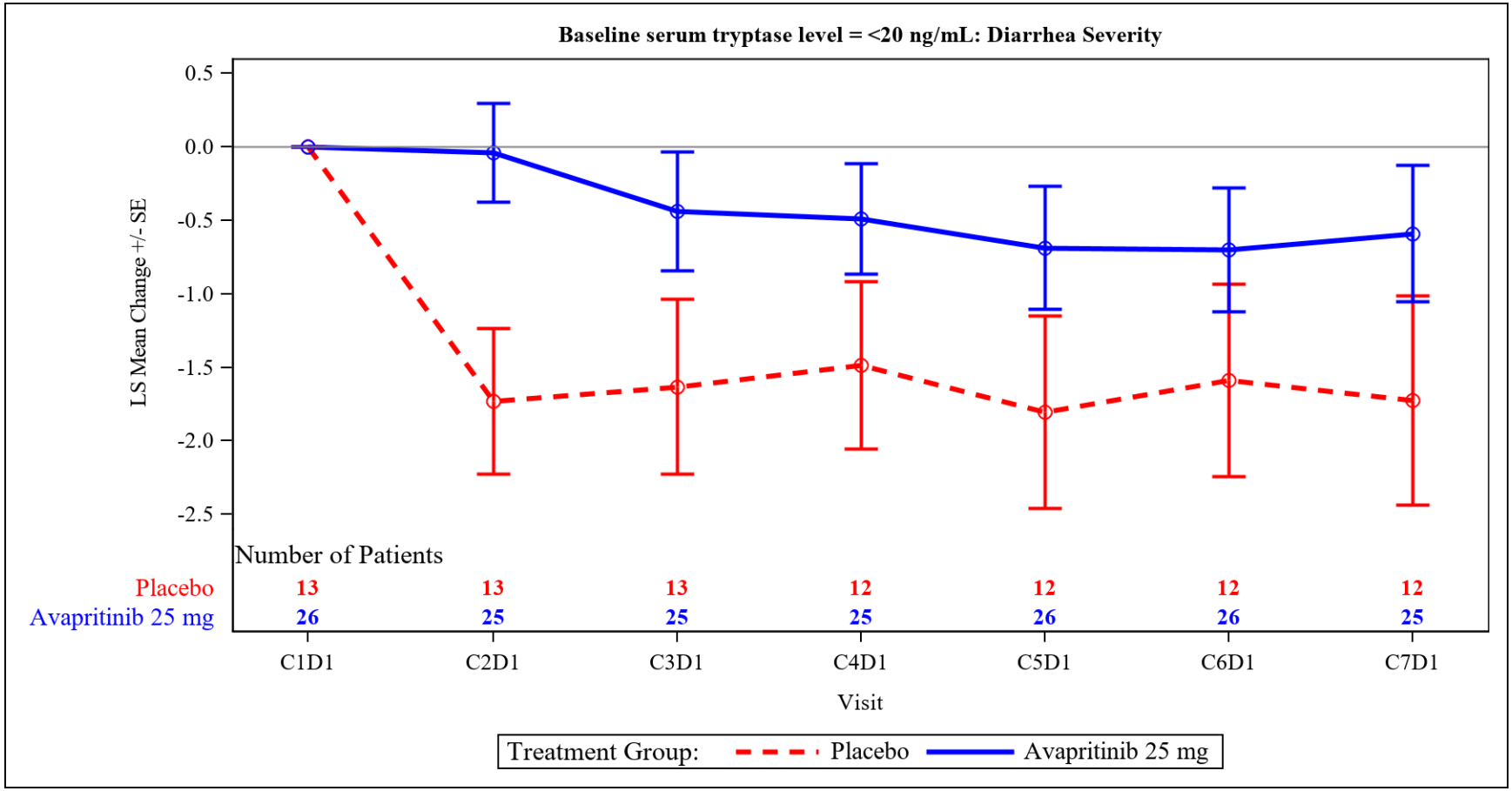
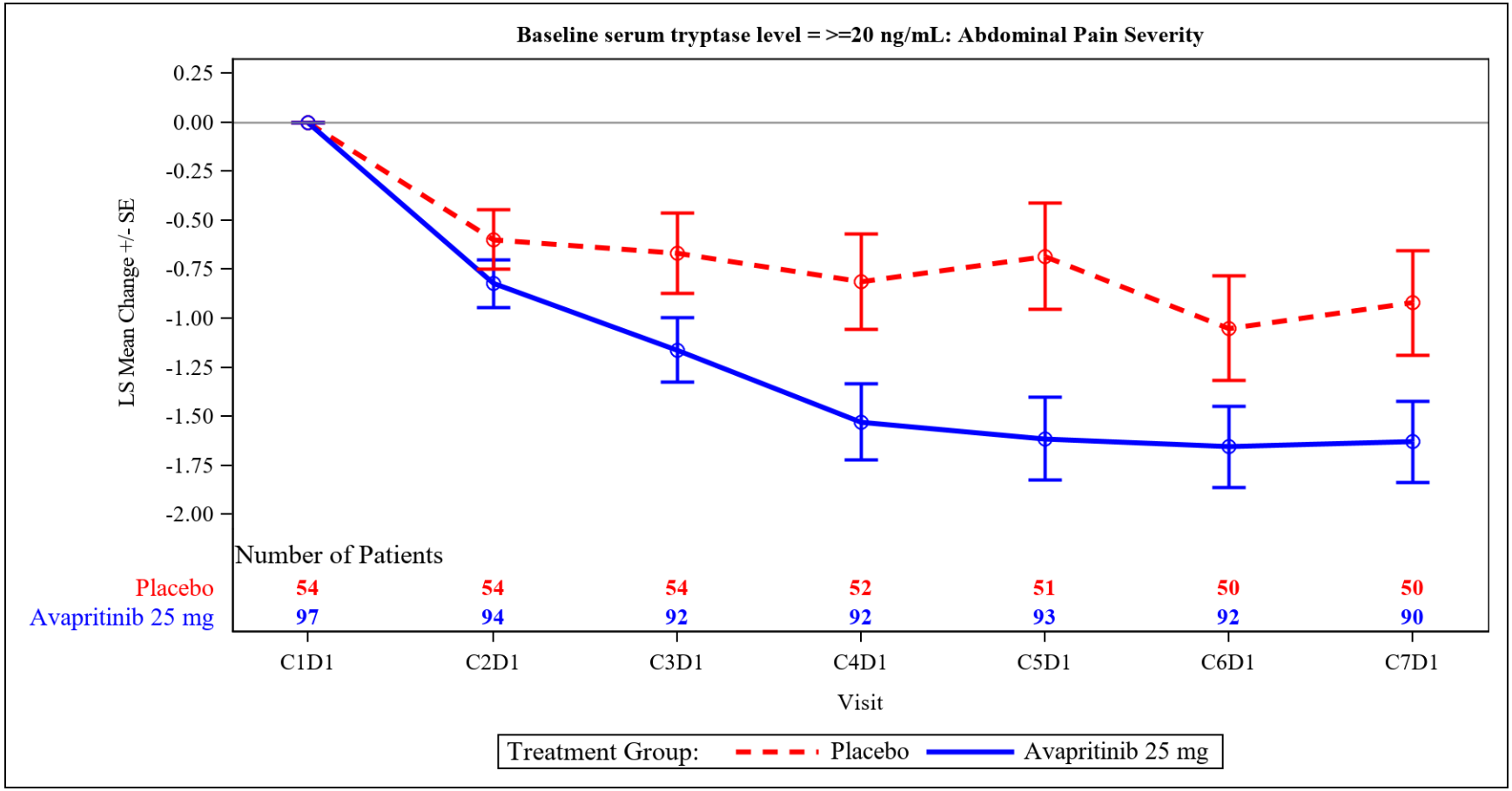
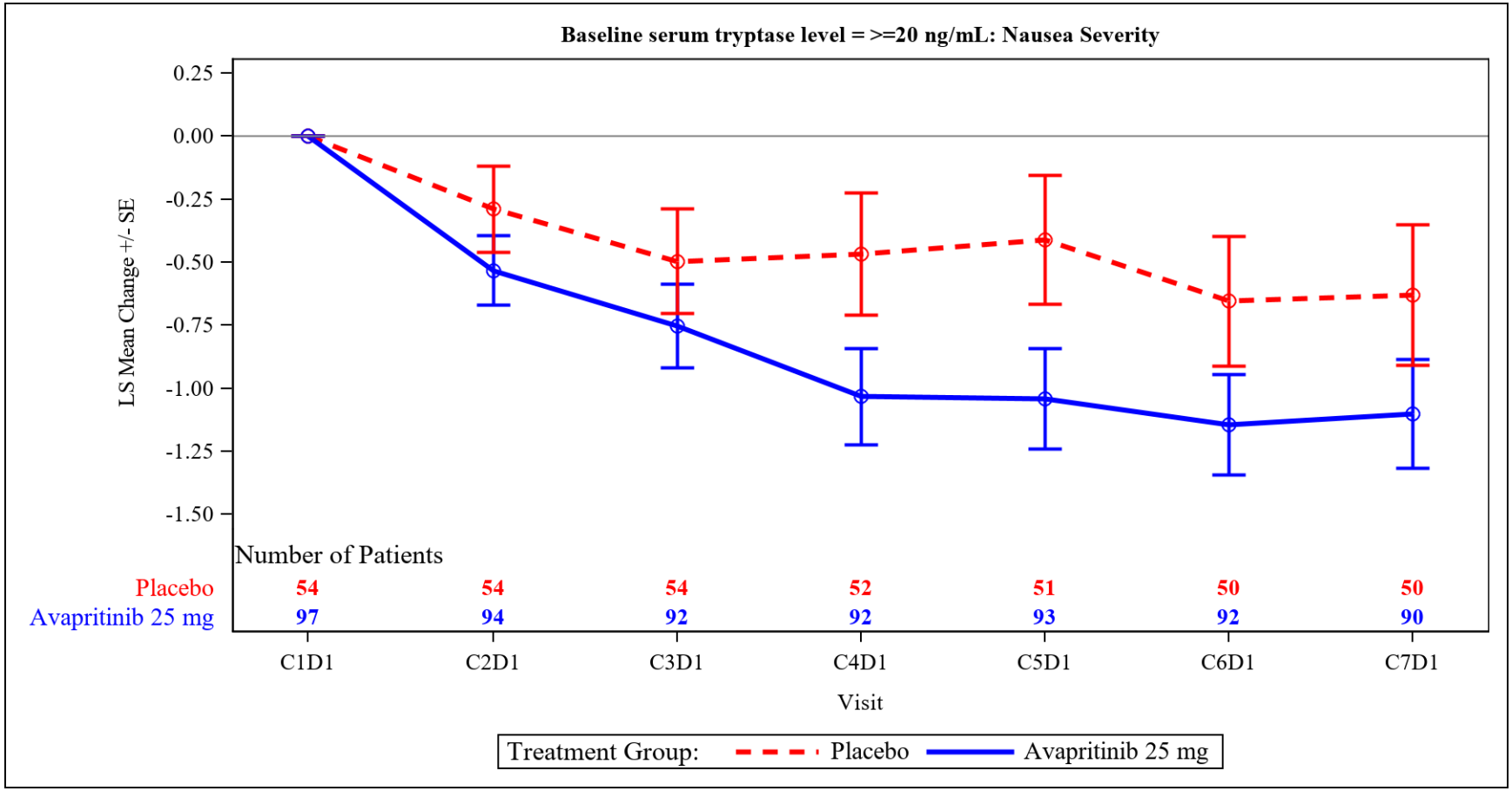


Figure 35.2.2.3.2.6a
LSMean Plot of Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)



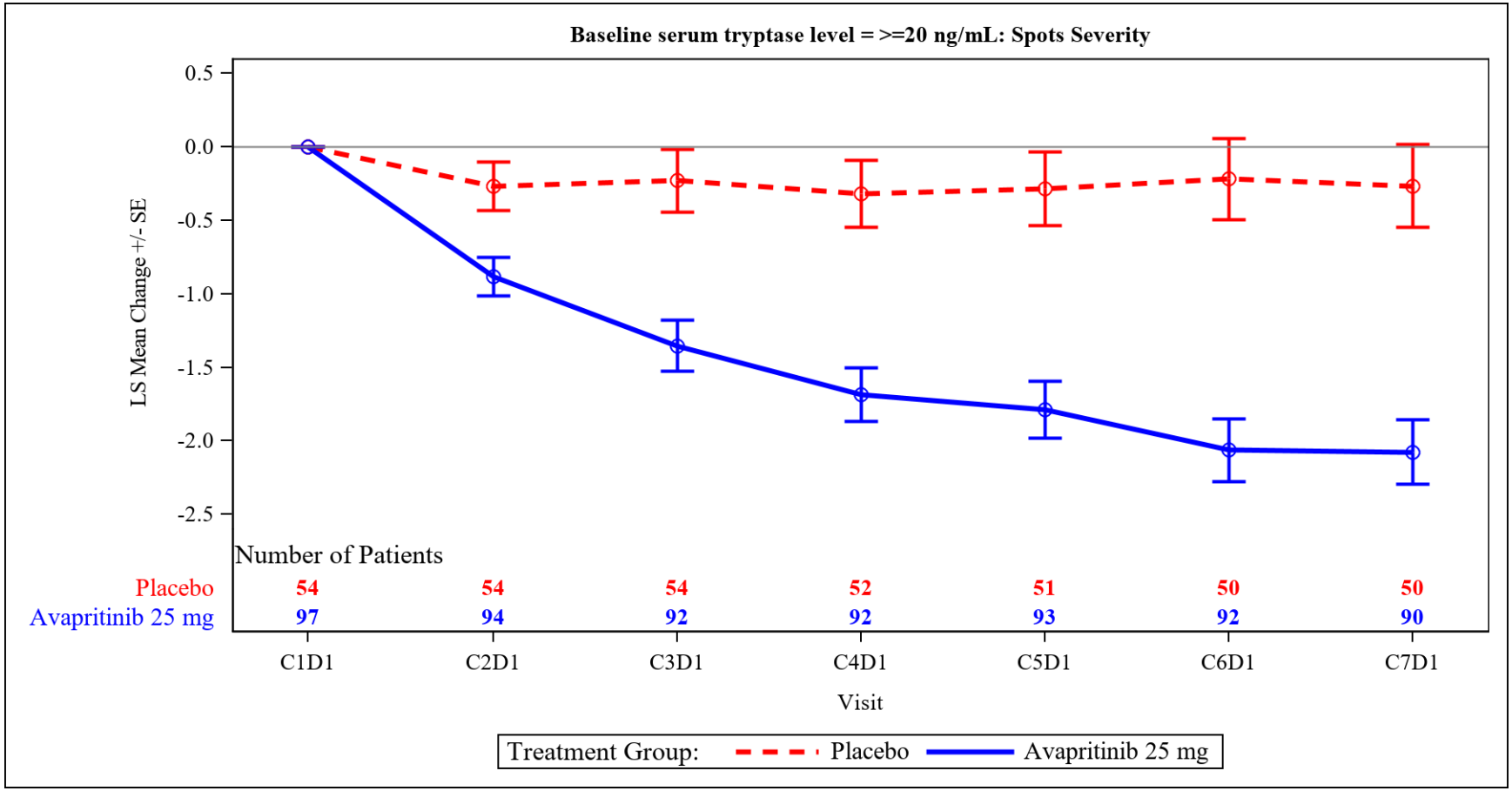
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-ismsaf-ind-sum-g-pp-tryp-a.sas Date: 16:26/07AUG2023

Figure 35.2.2.3.2.6a
LSMean Plot of Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)



Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-ismsaf-ind-sum-g-pp-tryp-a.sas Date: 16:26/07AUG2023

Figure 35.2.2.3.2.6a
LSMean Plot of Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)



Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-ismsaf-ind-sum-g-pp-tryp-a.sas Date: 16:26/07AUG2023

Figure 35.2.2.3.2.6a
LSMean Plot of Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

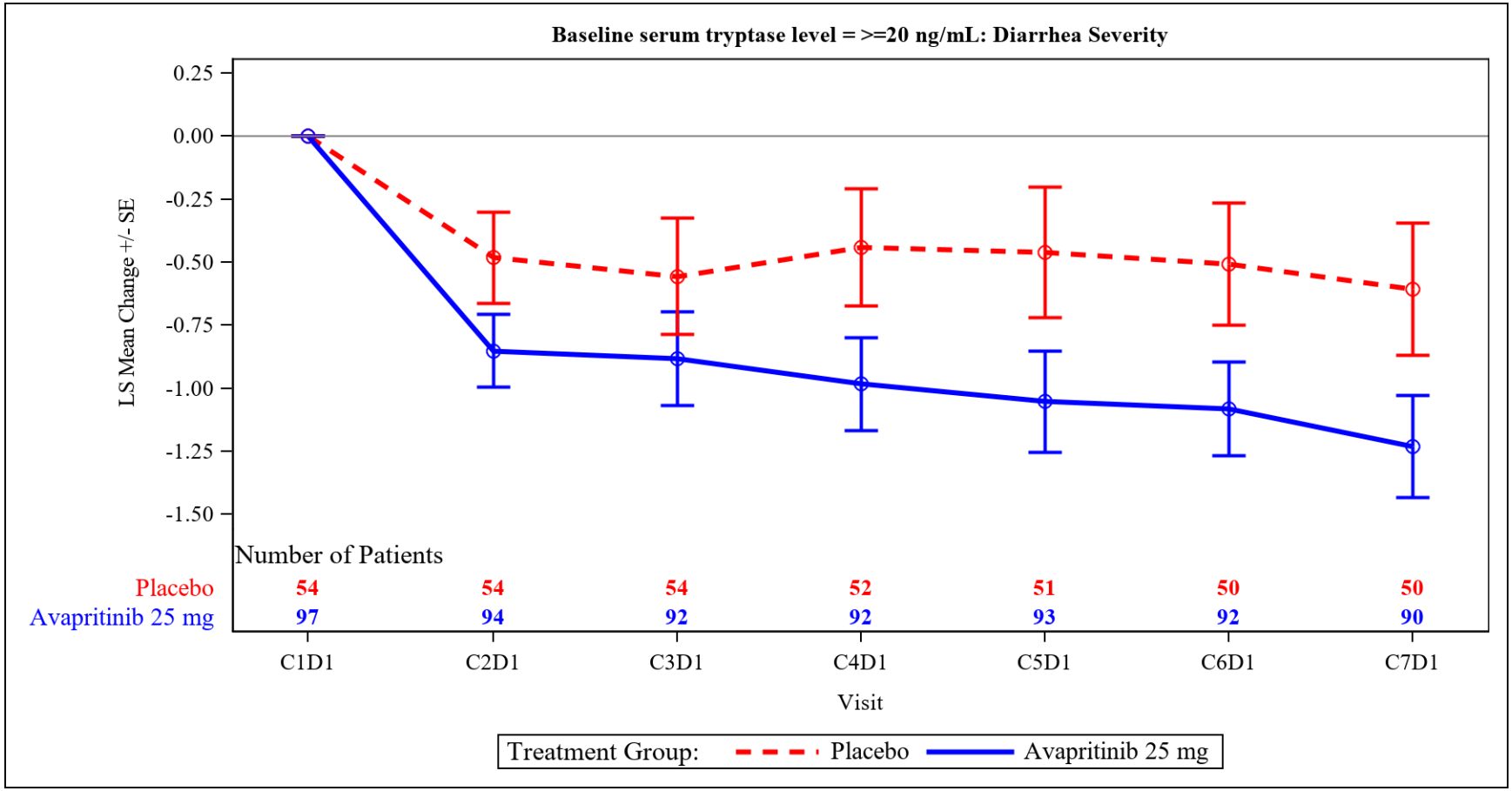


Figure 35.2.2.4.4.2.6a
LSMean Plot of Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

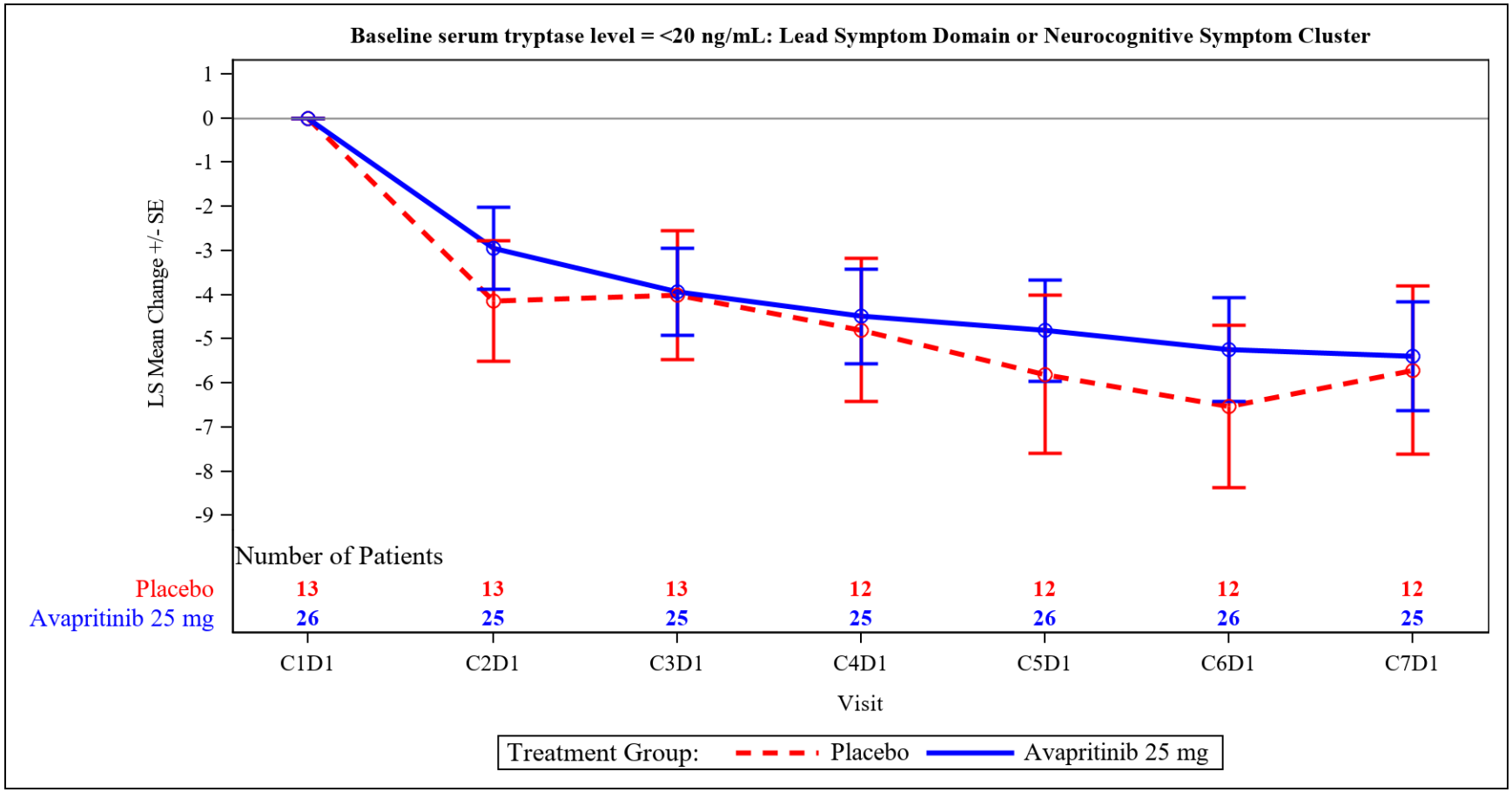


Figure 35.2.2.4.4.2.6a
LSMean Plot of Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

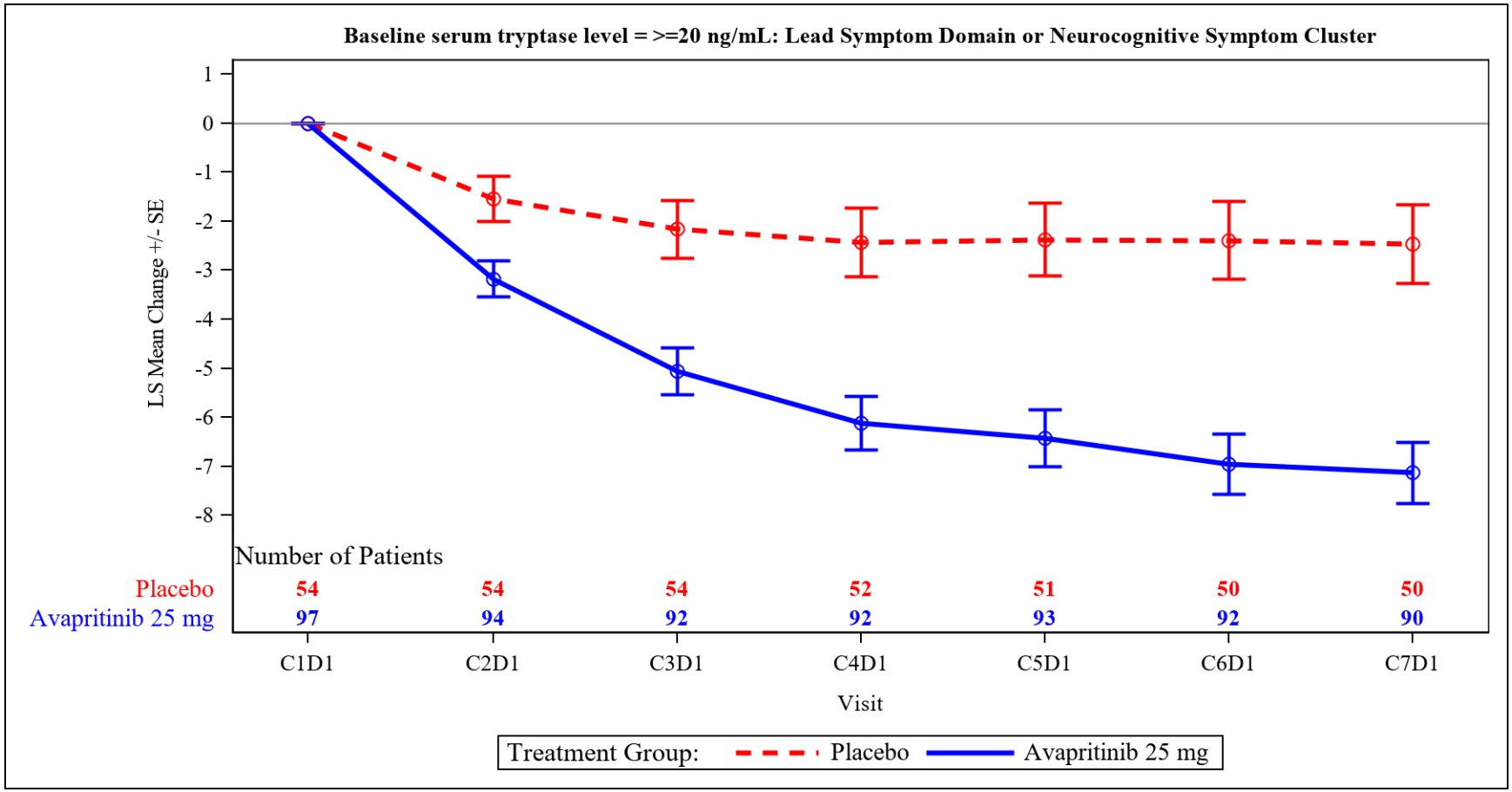


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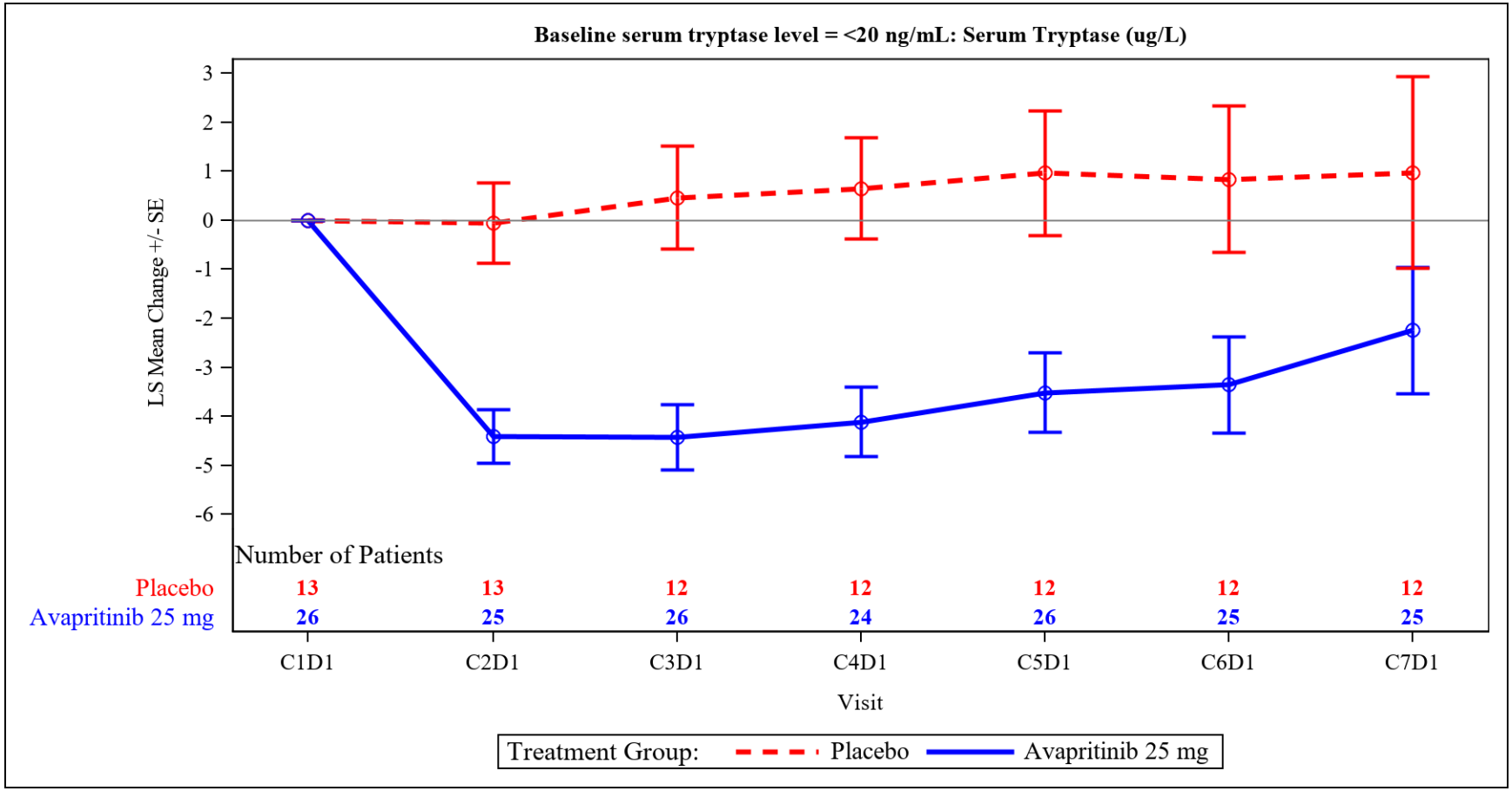
Figure 35.2.3.2.2.6a
LSMean Plot of Change from Baseline in Serum Tryptase (ng/mL) by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)



Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-tryp-sum-g-pp-tryp-a.sas Date: 16:30/07AUG2023

Figure 35.2.3.2.2.6a
LSMean Plot of Change from Baseline in Serum Tryptase (ng/mL) by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

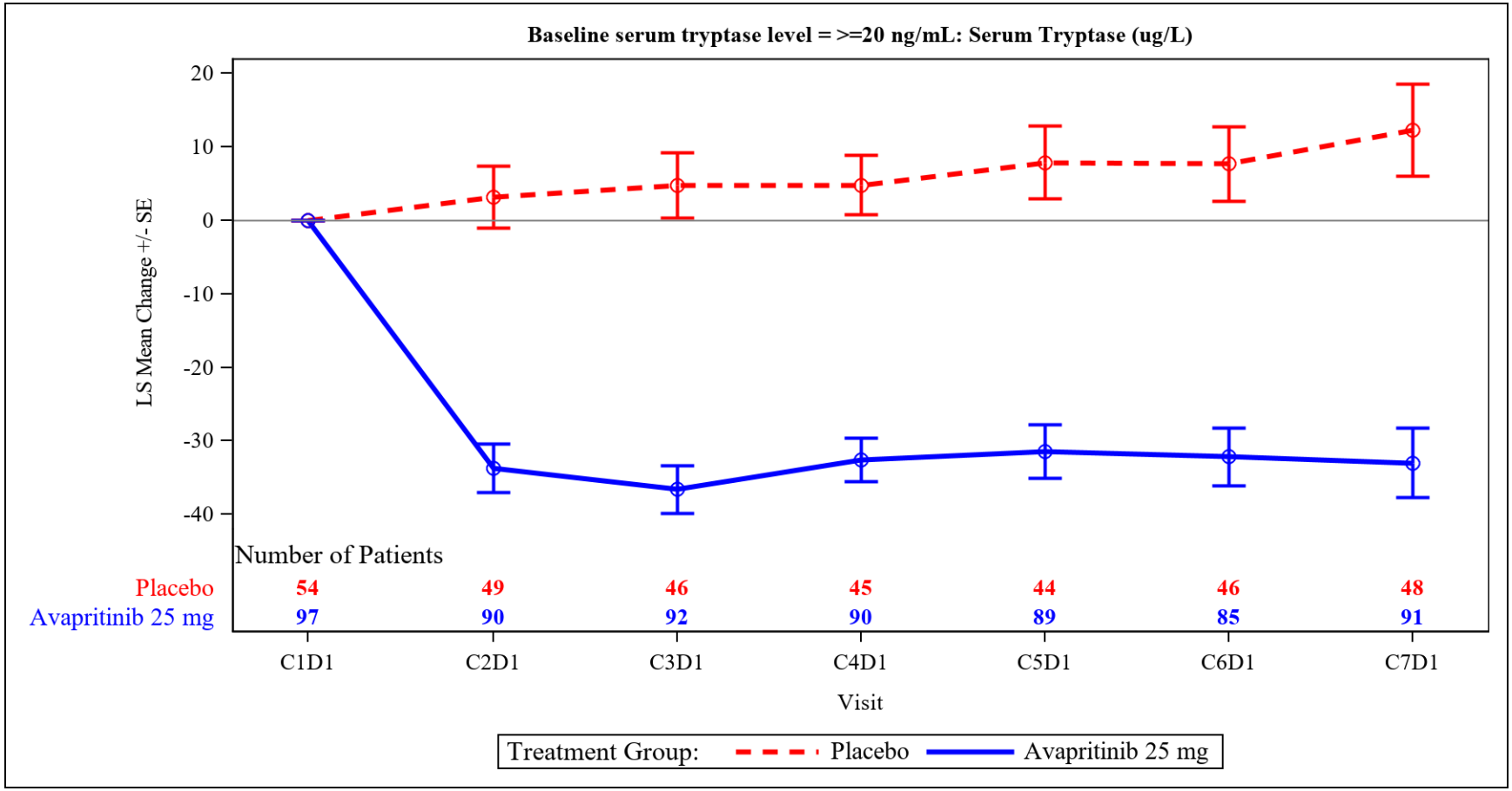


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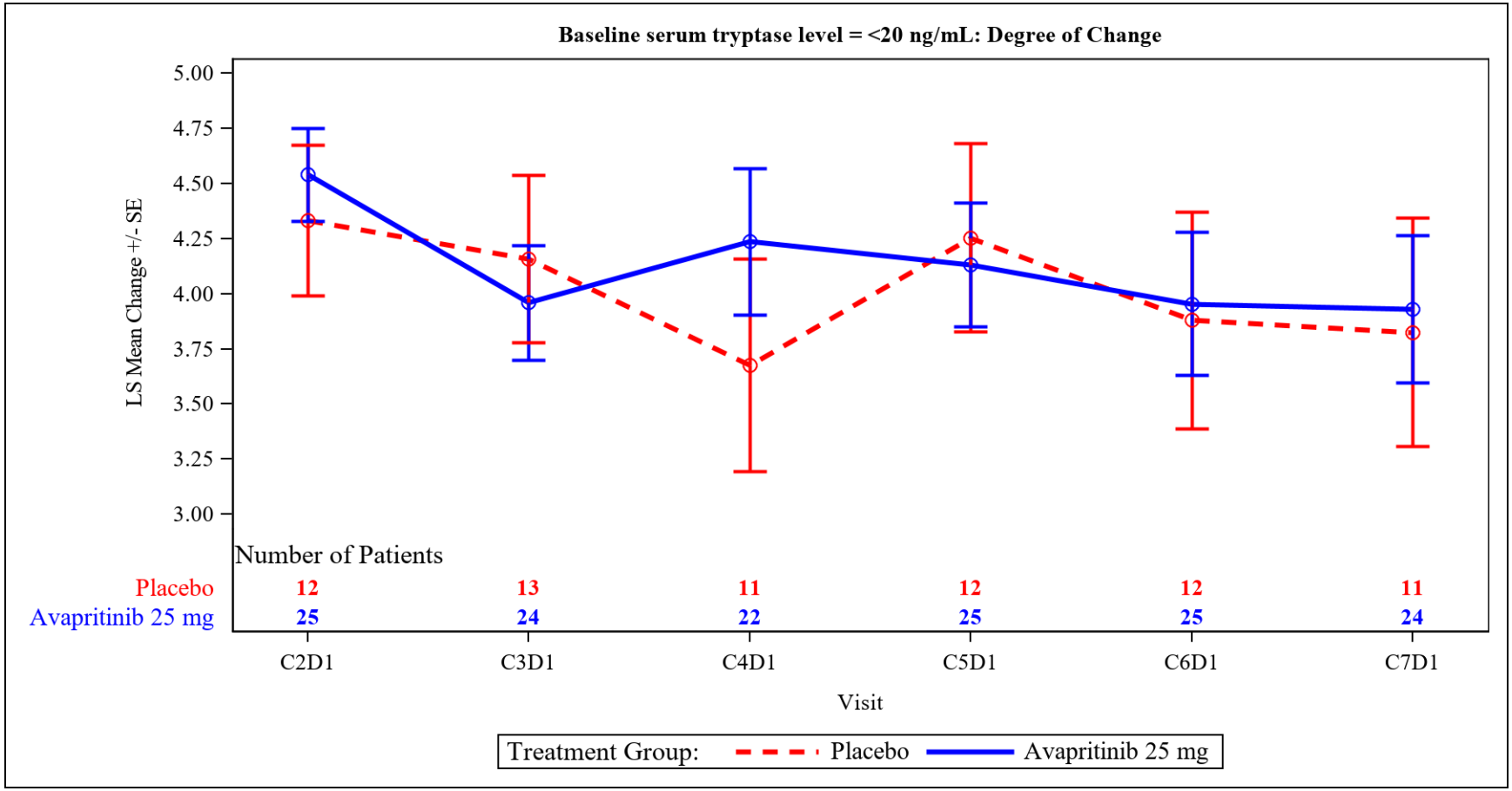
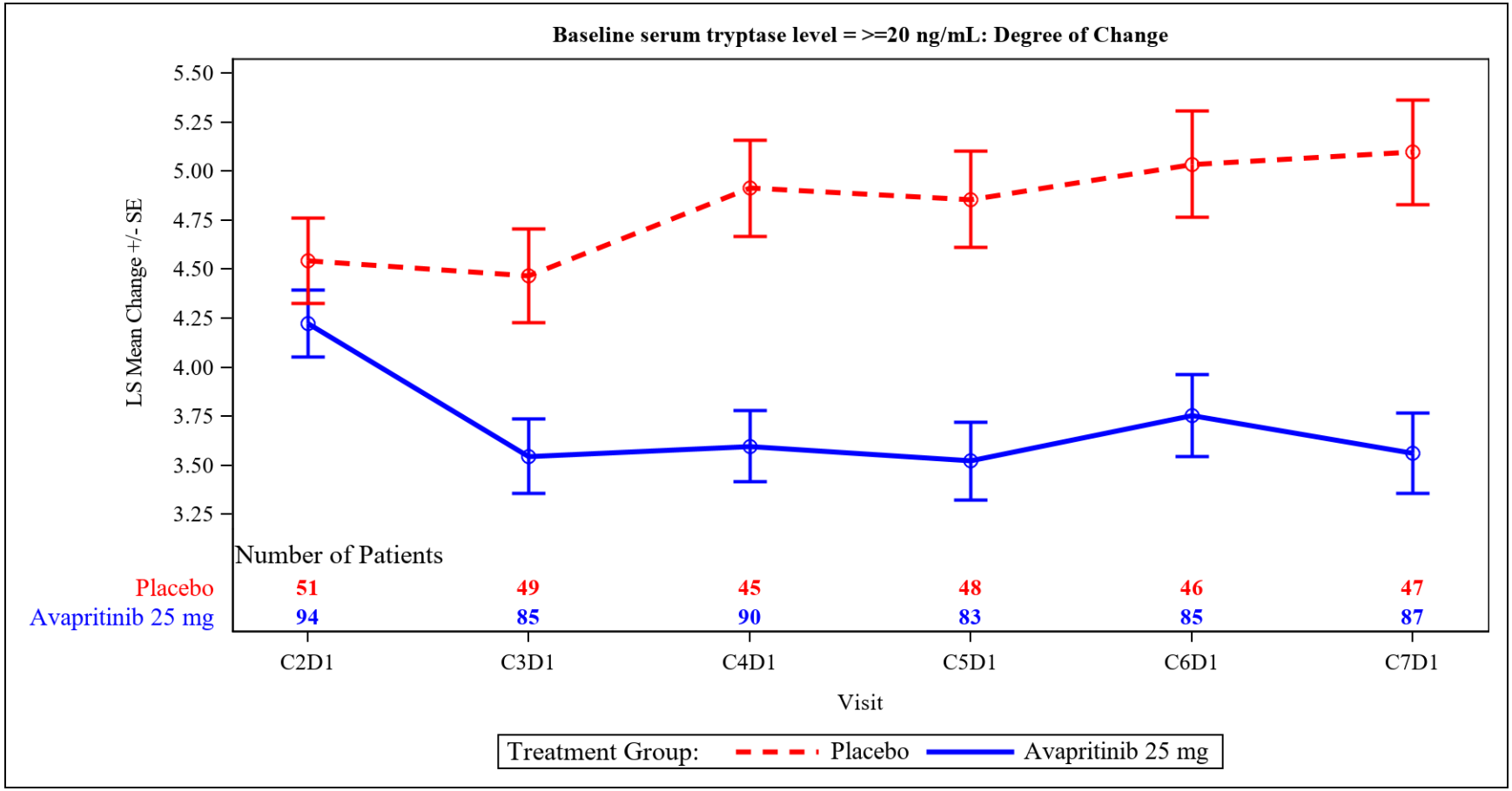
Figure 35.2.7.2.6a
LSMean Plot of PGIC by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)



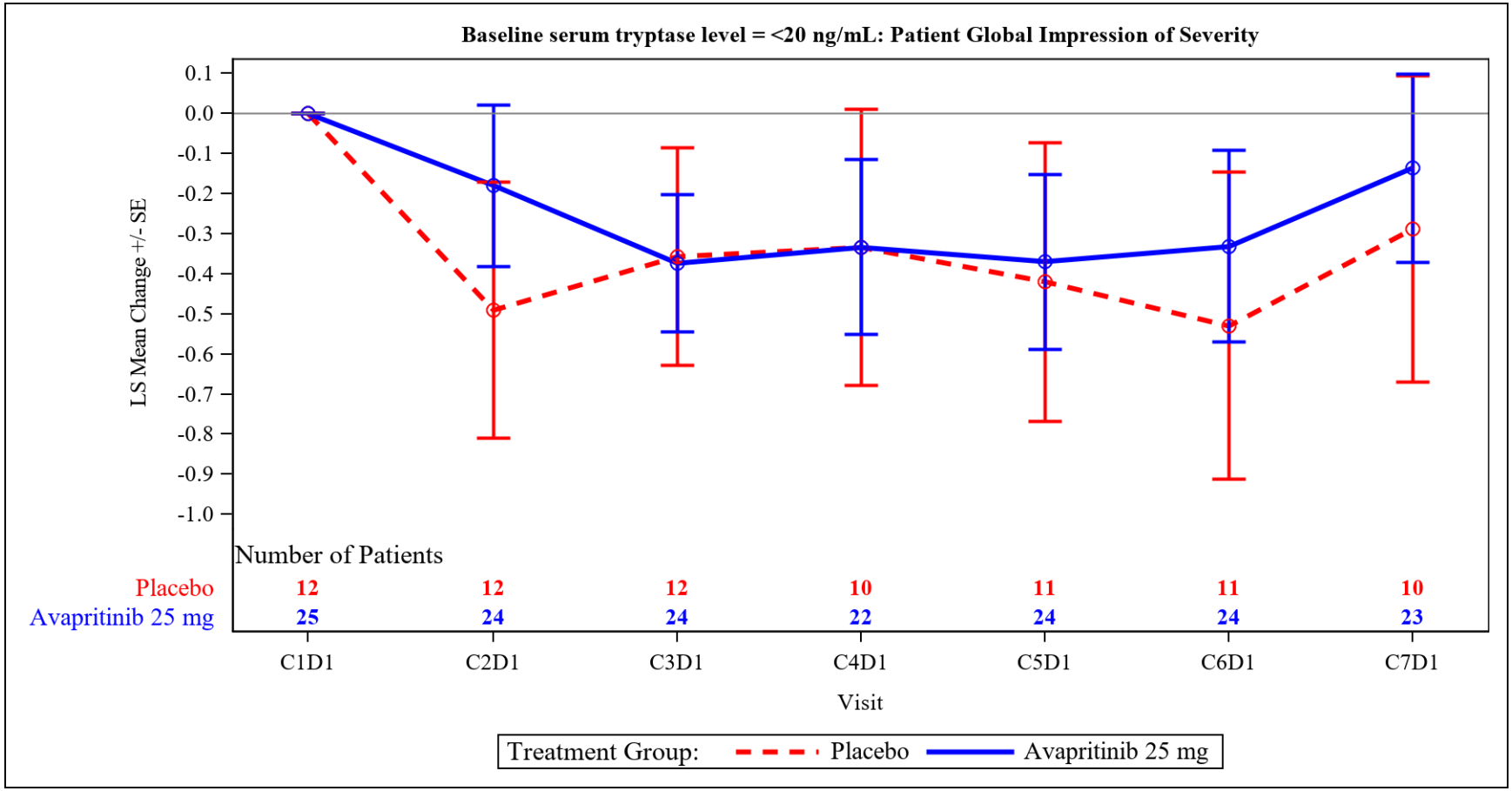
Patient Global Impression of Change Scale: 1=No change, 2=Almost the same, 3=A little better, 4=Somewhat better, 5=Moderately Better, 6=Better, 7=A great deal better.
Degree of Change is in the range of 0 to 10, with 0 = much better and 10 = much worse.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-pgic-sum-g-pp-tryp-a.sas Date: 16:31/07AUG2023

Figure 35.2.7.2.6a
LSMean Plot of PGIC by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)



Patient Global Impression of Change Scale: 1=No change, 2=Almost the same, 3=A little better, 4=Somewhat better, 5=Moderately Better, 6=Better, 7=A great deal better.
Degree of Change is in the range of 0 to 10, with 0 = much better and 10 = much worse.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-pgic-sum-g-pp-tryp-a.sas Date: 16:31/07AUG2023

Figure 35.2.6.2.6a
LSMean Plot of PGIS by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)



Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-pgis-sum-g-pp-tryp-a.sas Date: 16:30/07AUG2023

Figure 35.2.6.2.6a
LSMean Plot of PGIS by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

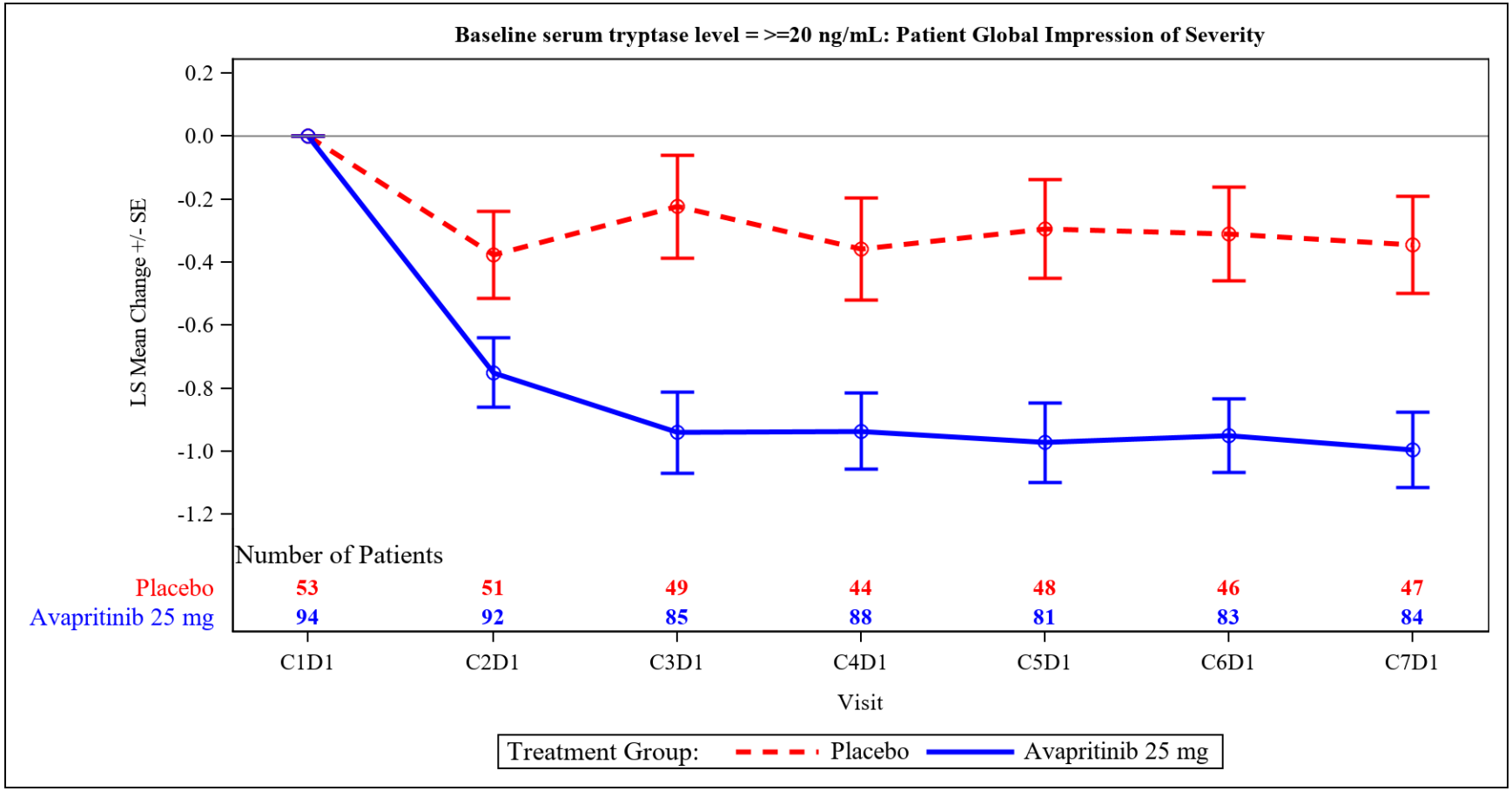


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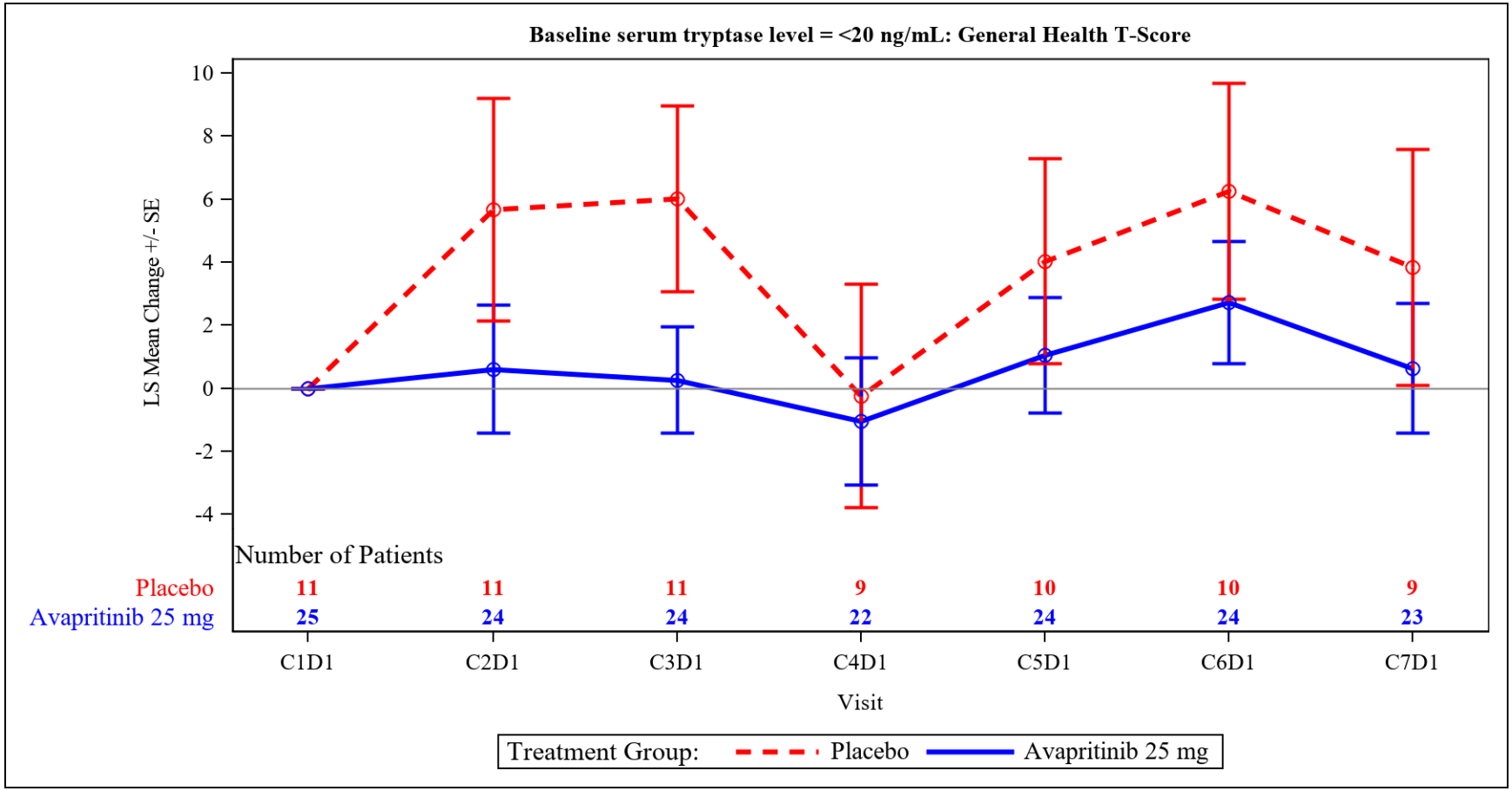
Figure 35.2.10.2.6a
LSMean Plot of Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)



Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-sf12-g-pp-tryp-a.sas
Date: 16:32/07AUG2023

Figure 35.2.10.2.6a
LSMean Plot of Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Per-Protocol Population, Part 2 (Part 2 Baseline)

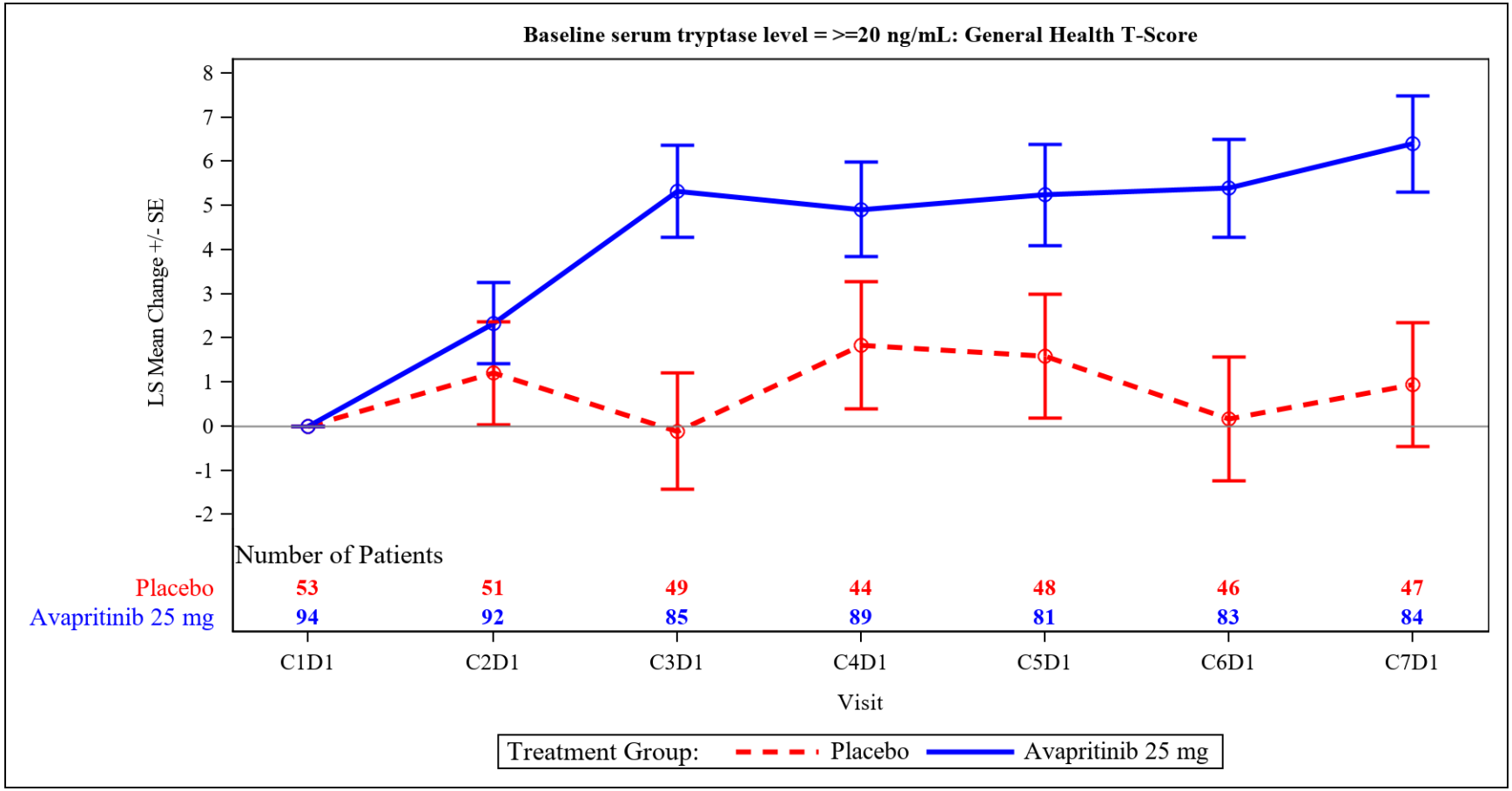


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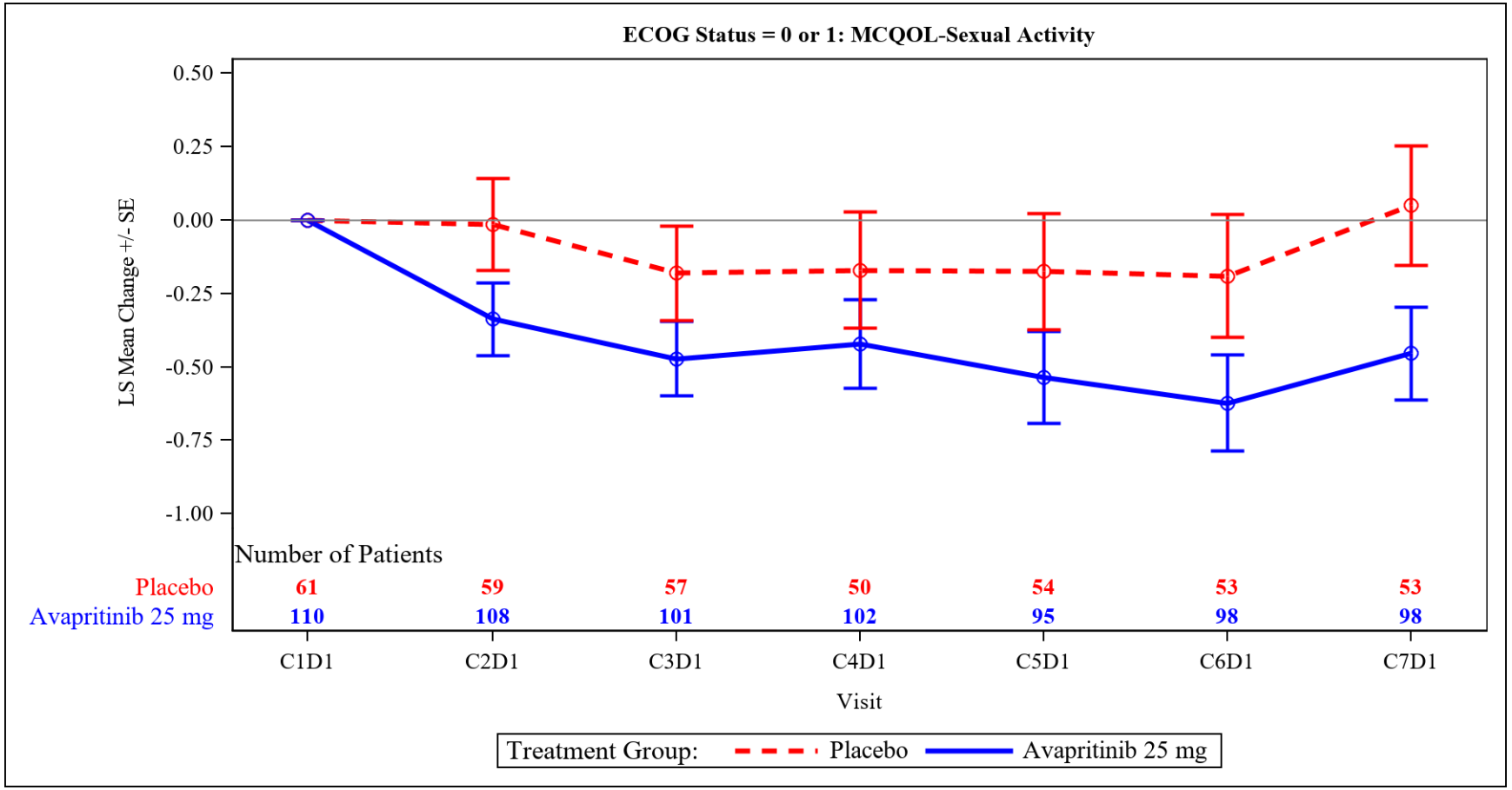
Figure 35.2.12.2.7a
LSMean Plot of Change from Baseline in Individual MC-QoL by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)



Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-mcqol-ind-g-pp-ecog-a.sas Date: 16:34/07AUG2023

Figure 35.2.12.2.7a
LSMean Plot of Change from Baseline in Individual MC-QoL by ECOG Status
Per-Protocol Population, Part 2 (Part 2 Baseline)

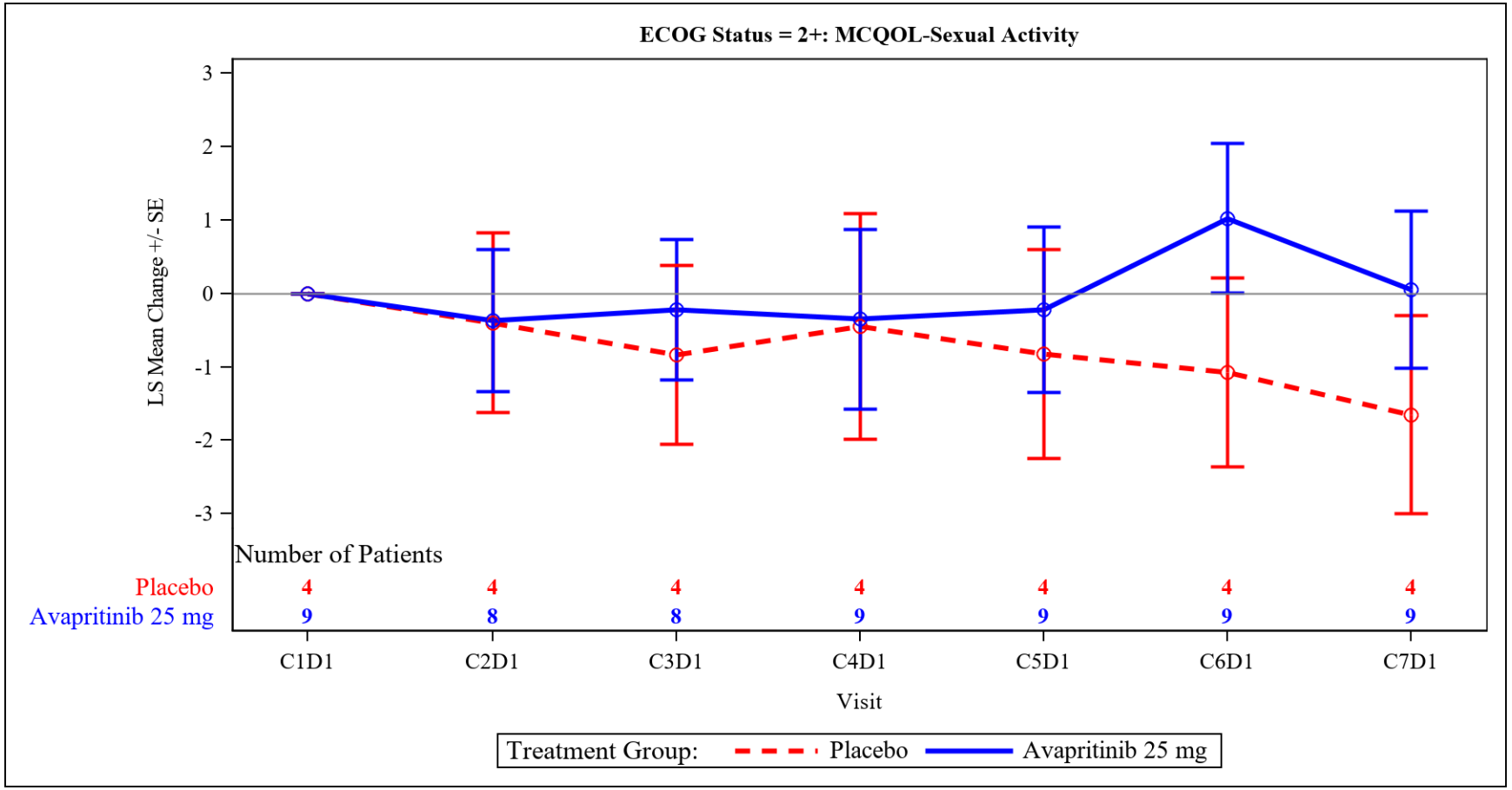


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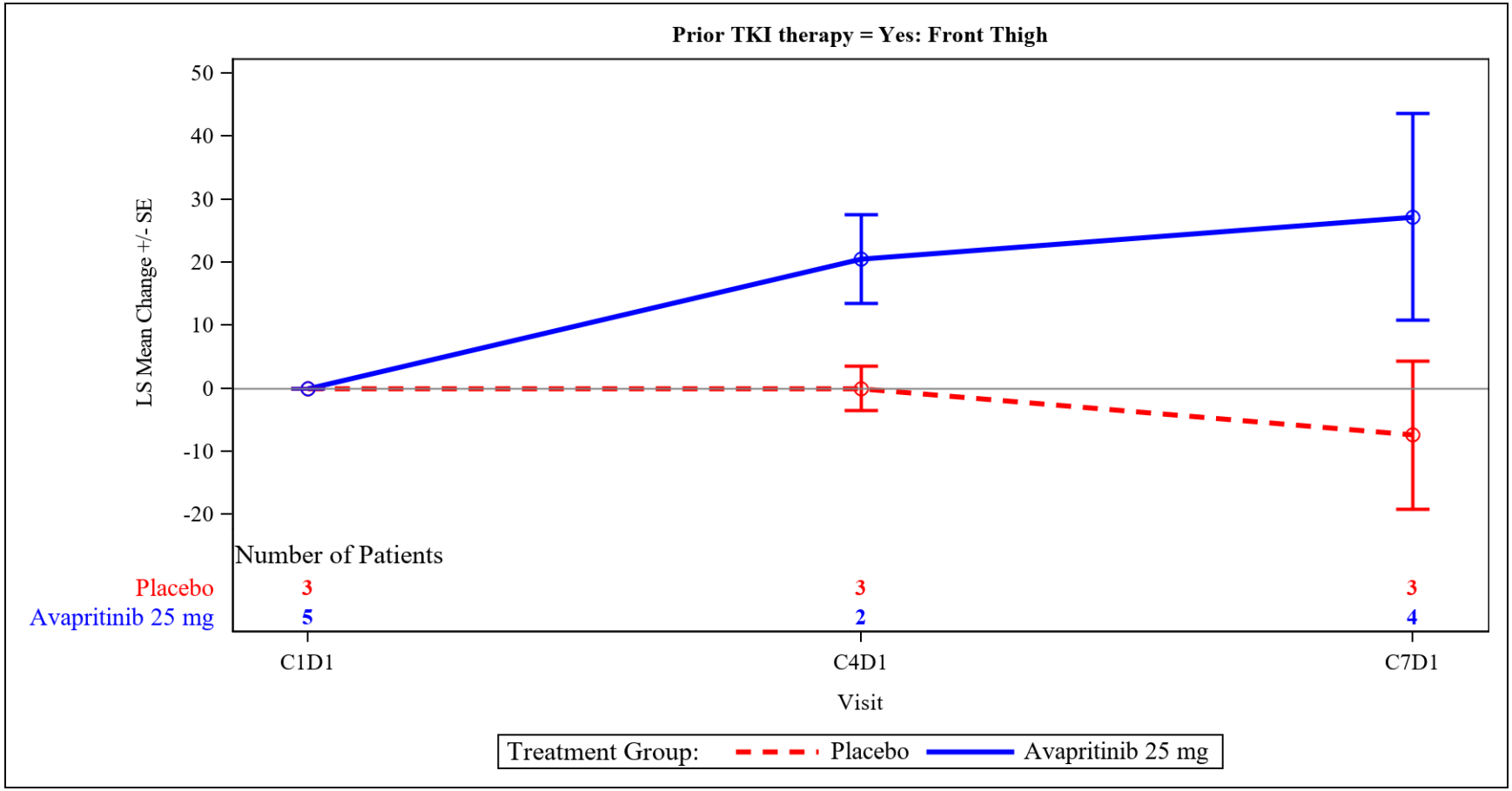
Figure 35.2.11.4.2.8a
LSMean Plot of Mastocytosis in Skin by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)



Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-mast-skin-g-pp-thpy-a.sas Date: 16:32/07AUG2023

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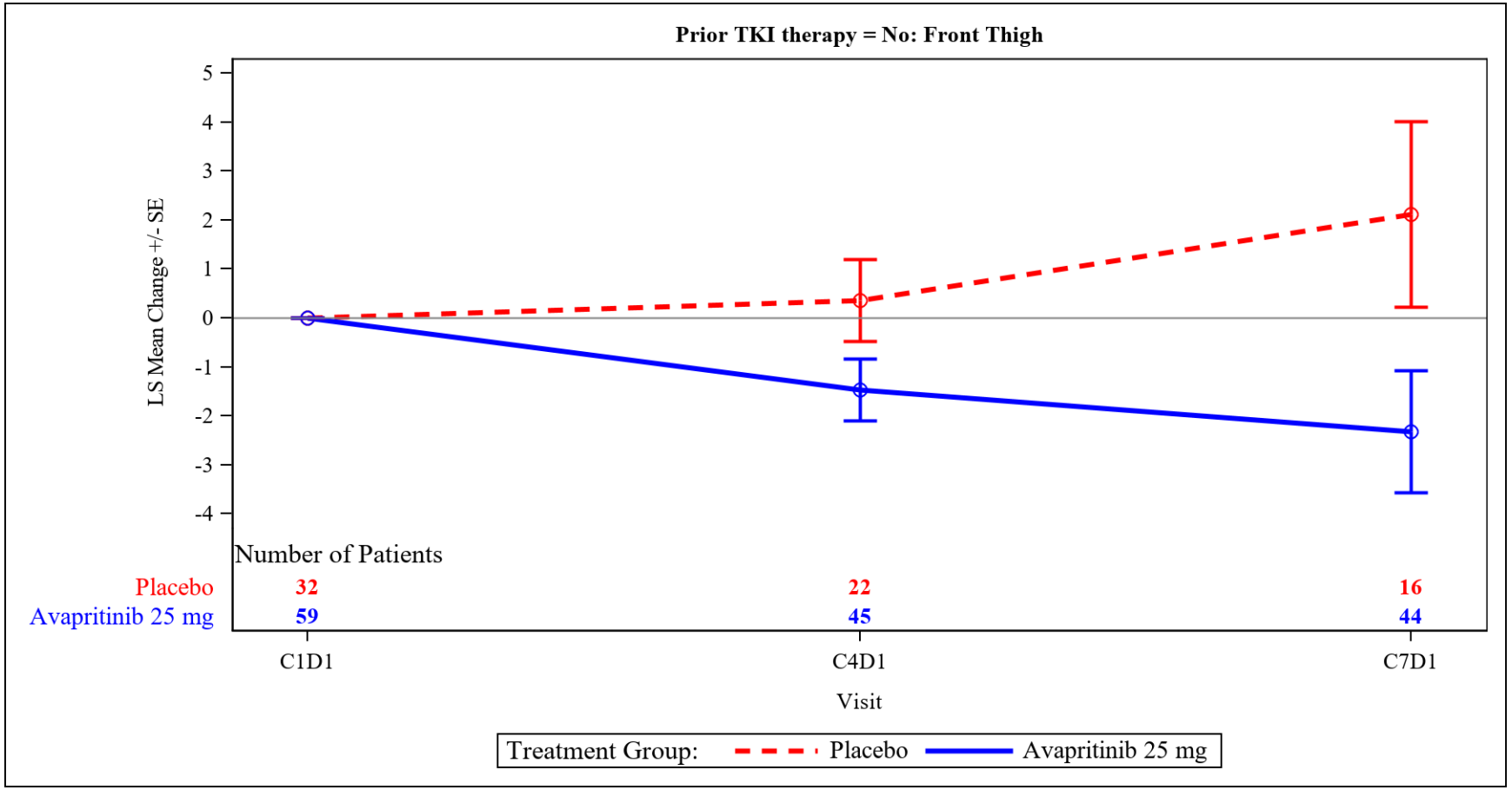
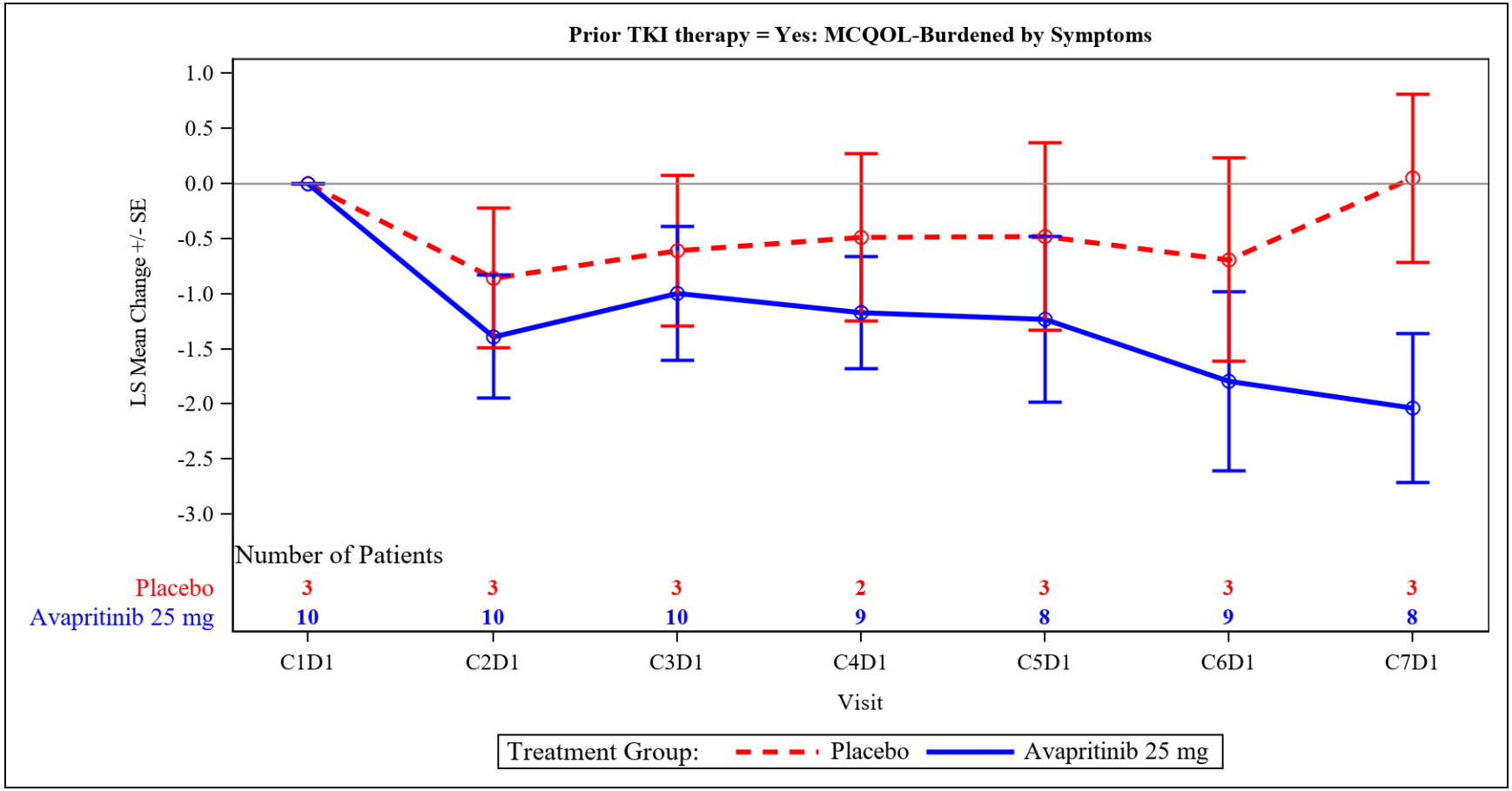
Figure 35.2.11.4.2.8a
LSMean Plot of Mastocytosis in Skin by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)



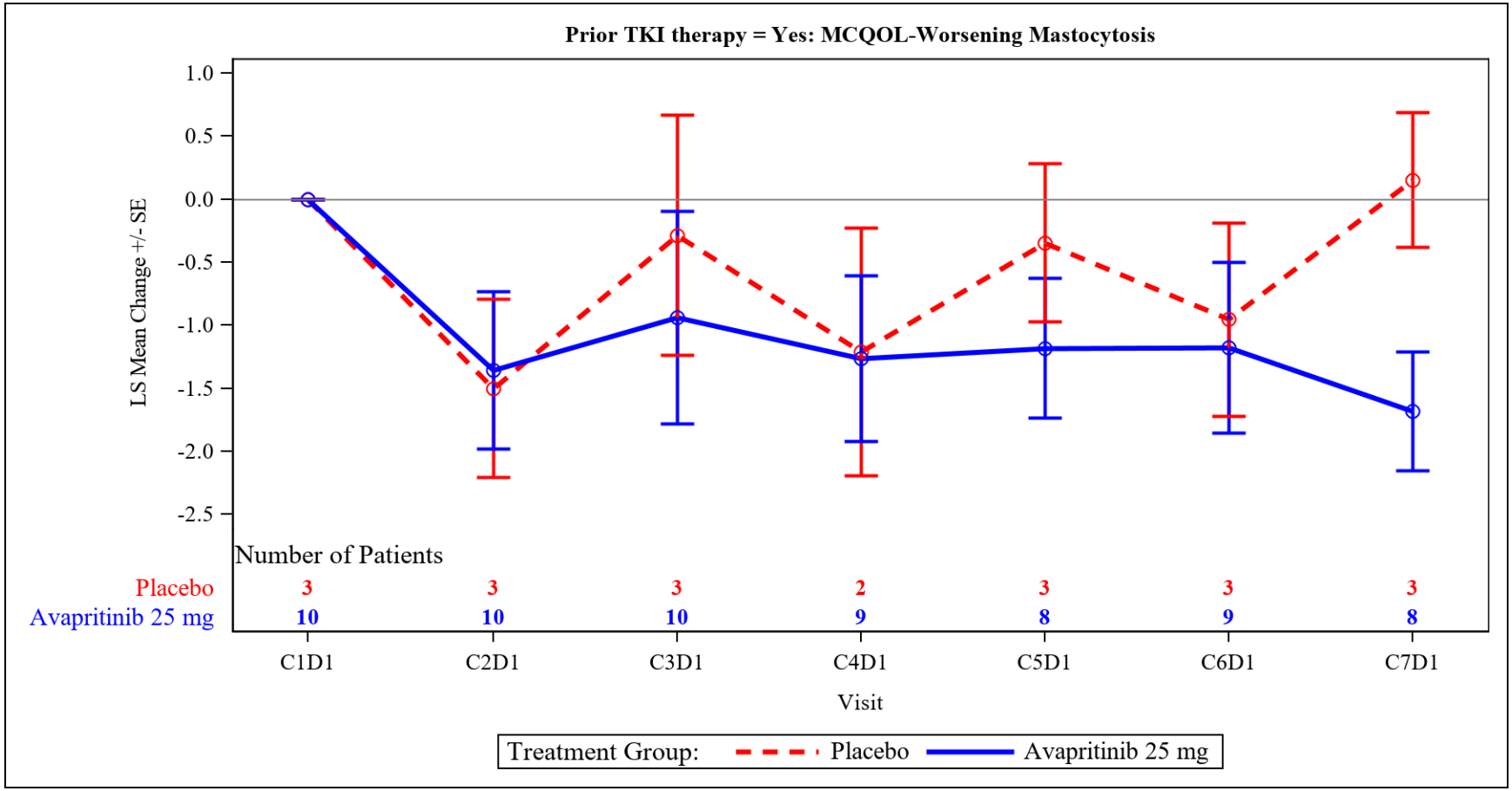
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-mast-skin-g-pp-thpy-a.sas Date: 16:32/07AUG2023

Figure 35.2.12.2.8a
LSMean Plot of Change from Baseline in Individual MC-QoL by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)



Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-mcqol-ind-g-pp-thpy-a.sas Date: 16:34/07AUG2023

Figure 35.2.12.2.8a
LSMean Plot of Change from Baseline in Individual MC-QoL by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)



Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-mcqol-ind-g-pp-thpy-a.sas Date: 16:34/07AUG2023

Figure 35.2.12.2.8a
LSMean Plot of Change from Baseline in Individual MC-QoL by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

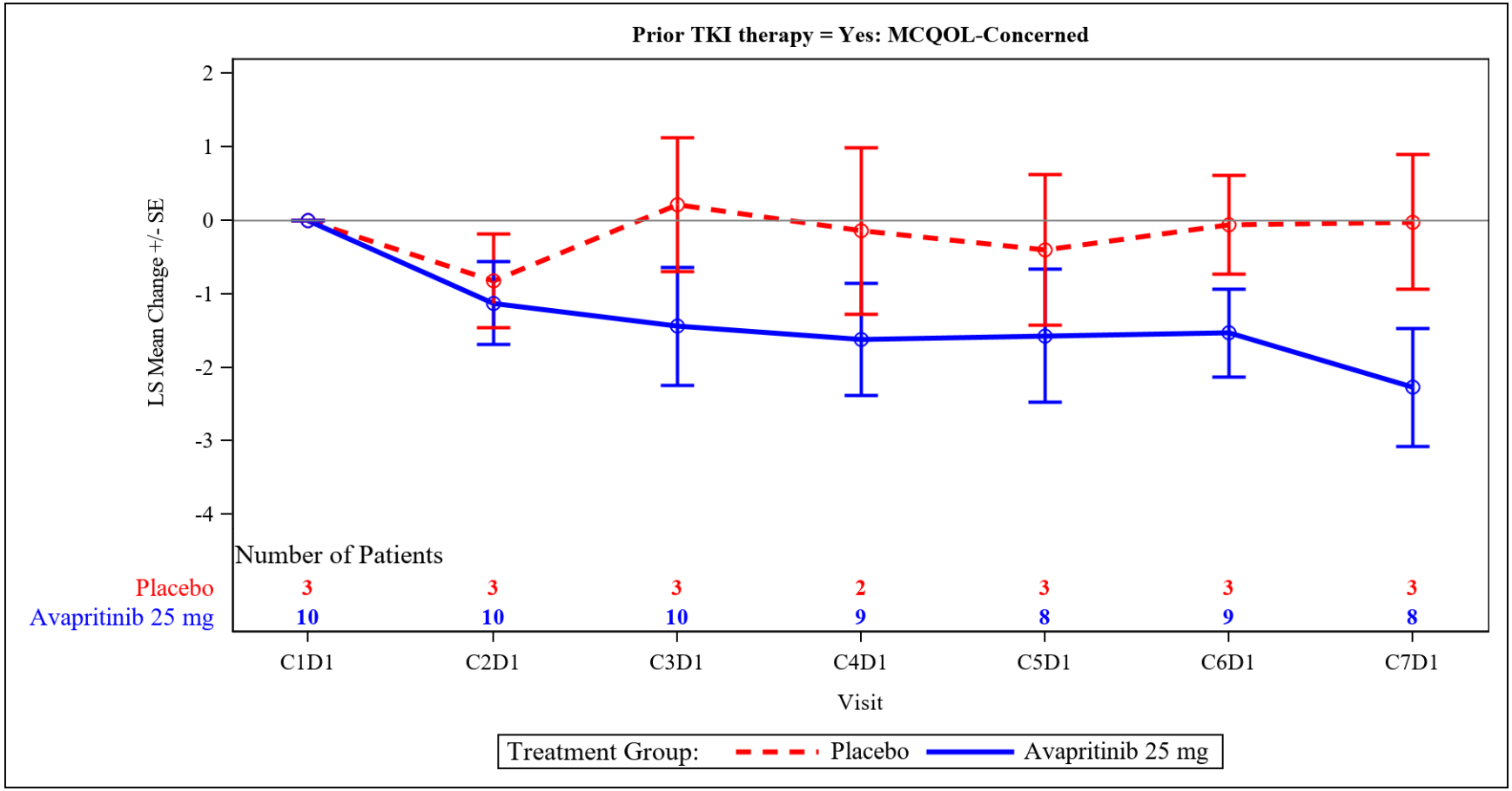
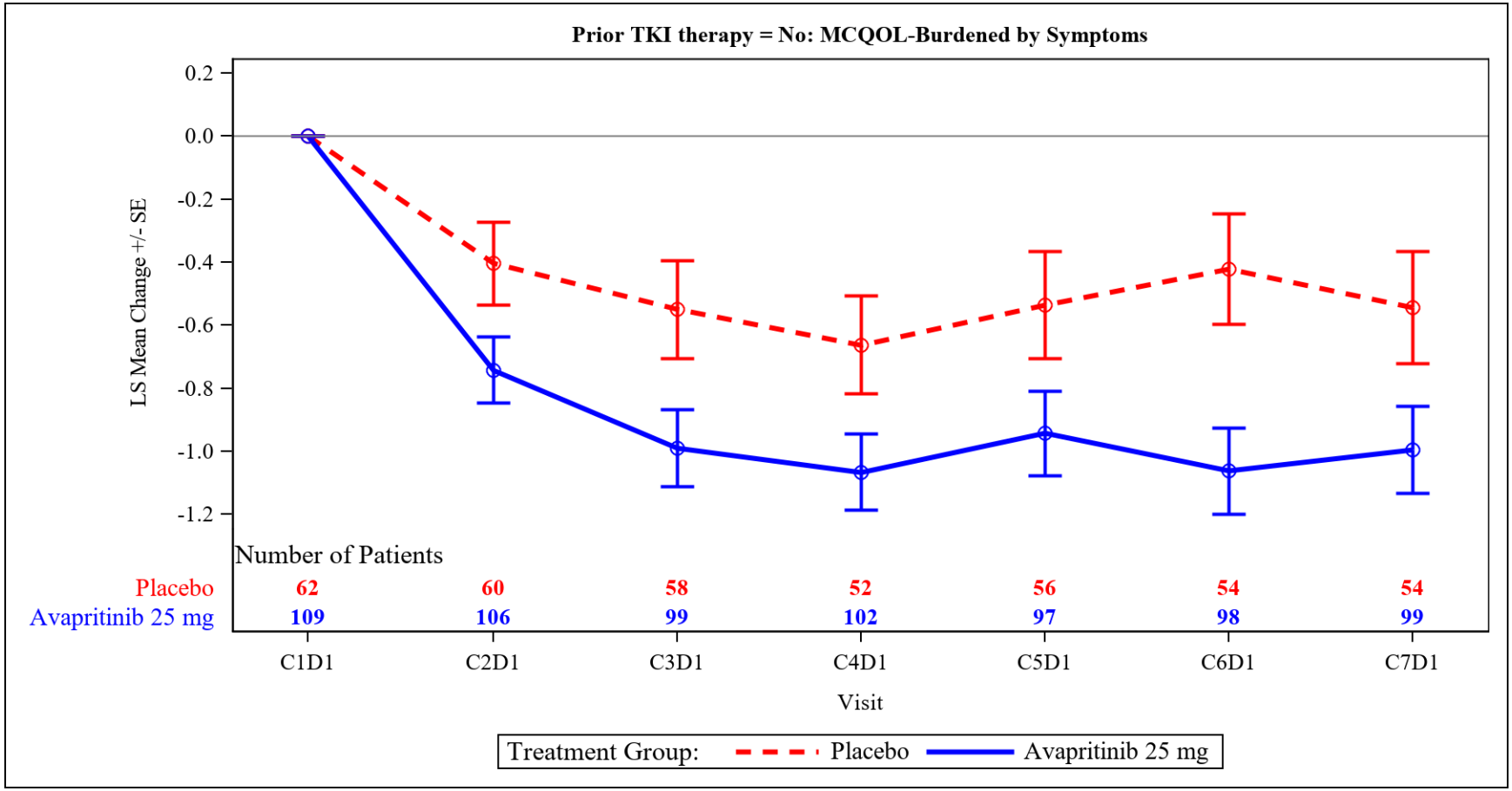


Figure 35.2.12.2.8a
LSMean Plot of Change from Baseline in Individual MC-QoL by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)



Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-mcqol-ind-g-pp-thpy-a.sas Date: 16:34/07AUG2023

Figure 35.2.12.2.8a
LSMean Plot of Change from Baseline in Individual MC-QoL by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)

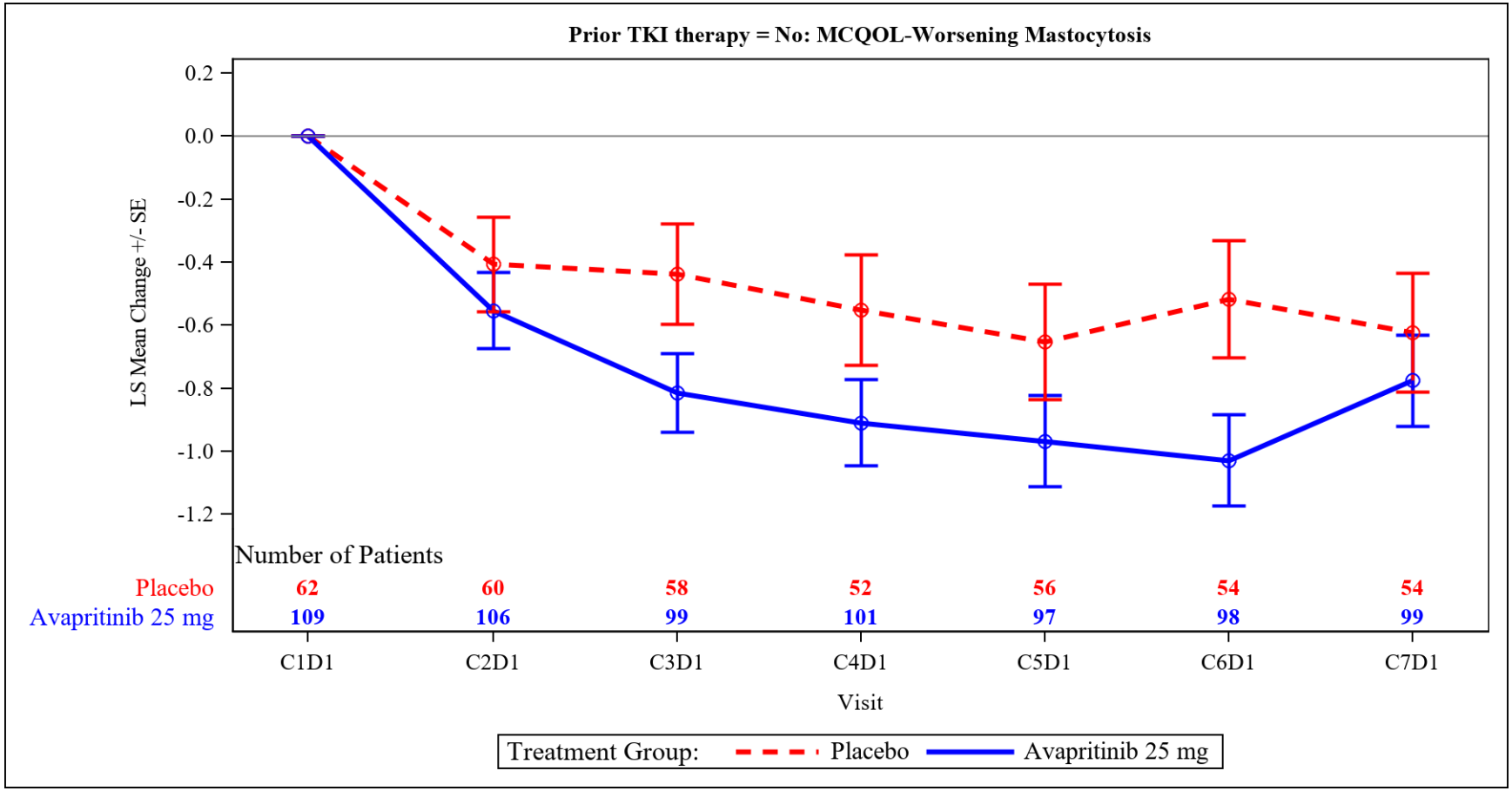


Figure 35.2.12.2.8a
LSMean Plot of Change from Baseline in Individual MC-QoL by Prior TKI Therapy
Per-Protocol Population, Part 2 (Part 2 Baseline)